Justice and Beneficence in Military Medicine and Research

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This Article examines the extent to which U.S. law promotes justice and beneficence in military medicine and research. I begin by reviewing the historical development of experimental studies in the military and the egregious research methods employed by the U.S. government under the guise of national security. I then analyze socio-medical implications of contemporary military medicine by evaluating investigational use of medical products and biomedical enhancements. I conclude by proposing reforms that aim to harmonize national security interests with fundamental principles of patient autonomy and human dignity. The proposals include amendments to the legal and regulatory framework governing military medicine and research, enhanced medical monitoring and post-research care, and statutory limitations to sovereign immunity.

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I. INTRODUCTION

The United States military has a long and checkered history of experimental research involving human subjects. It has sponsored clandestine projects that examined if race influences one's susceptibility to mustard gas,[1] the extent to which radiation affects combat effectiveness,[2] and whether psychotropic drugs could be used to facilitate interrogations or develop chemical weapons.[3] In each of these experiments, the government deliberately violated legal requirements and ethical norms that govern human-subjects research and failed to provide adequate follow-up medical care or compensation for those who suffered adverse health effects. In defending its decisions, the government argued that the studies and research methods were necessary to further the strategic advantage of the United States.[4]

The military's contemporary research program is motivated by the same rationale. As the U.S. Defense Advanced Research Projects Agency (DARPA) explains, its goal is to "create strategic surprise for U.S. adversaries by maintaining the technological superiority of the U.S. military."[5] Current research sponsored by DARPA and the U.S. Department of Defense (DoD)

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[1] *See* Susan L. Smith, *Mustard Gas and American Race-Based Human Experimentation in World War II*, 36 J.L. MED. & ETHICS 517, 517 (2008).

[2] *See* ADVISORY COMM. ON HUMAN RADIATION EXPERIMENTS, FINAL REPORT OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS 14–15 (Oxford Univ. Press 1996) [hereinafter HUMAN RADIATION EXPERIMENTS REPORT].

[3] *See* David H. Price, *Buying a Piece of Anthropology*, 23 ANTHROPOLOGY TODAY, June 2007, at 8, 8–9.

[4] *See* Paul J. Amoroso & Lynn L. Wenger, *The Human Volunteer in Military Biomedical Research*, *in* 2 MILITARY MEDICAL ETHICS 563, 569 (Thomas E. Beam & Linette R. Sparachino eds., 2003).

[5] DEF. ADVANCED RESEARCH PROJECTS AGENCY, *Our Work*, http://www.darpa.mil/our_work/ (last visited Feb. 22, 2012). A related goal is "to prevent strategic surprise from negatively impacting U.S. national security." *Id.*

aims to ensure that soldiers have "no physical, physiological, or cognitive limitations."[6] The research includes drugs that keep soldiers awake for seventy-two hours or more, a nutraceutical that fulfills a soldier's dietary needs for up to five days, a vaccine that eliminates intense pain within seconds, and sophisticated brain-to-computer interfaces.[7]

The military's emphasis on neuroscience is particularly noteworthy, with recent annual appropriations of over $350 million for cognitive science research.[8] Projects include novel methods of scanning a soldier's brain to ascertain physical, intellectual, and emotional states, as well as the creation of electrodes that can be implanted into a soldier's brain for purposes of neuroanalysis and neurostimulation.[9] One of the goals of the research is to create a means by which a soldier's subjective experience can be relayed to a central command center, and, in turn, the command center can respond to the soldier's experience by stimulating brain function for both therapeutic and enhancement purposes.[10] For example, the electrodes can be used to activate brain function that can help heal an injury or keep a soldier alert during difficult moments.[11] Another goal is to create a "connected consciousness" whereby a soldier can interact with machines, access information from the Internet, or communicate with other humans via thought alone.[12]

In the context of military research, human subjects play an integral role in the development of new medicines and technologies. Although regulatory guidelines mandate that military physicians and researchers obtain voluntary and informed consent prior to experimentation on human subjects,[13] these protocols have not been followed faithfully. Moreover, in a number of instances, the DoD has sought and obtained informed consent waivers by

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[6] Catherine L. Annas & George J. Annas, *Enhancing the Fighting Force: Medical Research on American Soldiers*, 25 J. CONTEMP. HEALTH L. & POL'Y 283, 286 (2009).

[7] *See id.* at 285–86.

[8] Michael N. Tennison & Jonathan D. Moreno, *Neuroscience, Ethics, and National Security: The State of the Art*, 10 PLoS BIOLOGY, Mar. 2012, at 1, 1; *see also* JONATHAN D. MORENO, MIND WARS: BRAIN RESEARCH AND NATIONAL DEFENSE 4 (2006); Hannah Hoag, *Remote Control*, 423 NATURE 796, 796 (2003). Over the past decade, the "national security establishment has come to see neuroscience as a promising and integral component of its 21st century needs." Tennison & Moreno, *supra*, at 1. According to one researcher at the California Institute of Technology, "the military has always been visionary when funding neuroscience." MORENO, *supra*, at 15.

[9] *See* Hoag, *supra* note 8, at 796.

[10] *See id.*

[11] *See* MORENO, *supra* note 8, at 182.

[12] Annas & Annas, *supra* note 6, at 285–86.

[13] Federal Policy for the Protection of Human Subjects, 56 Fed. Reg. 28,003, 28,016 (June 18, 1991) [hereinafter Common Rule]; U.S. DEPT. OF DEF., Instruction No. 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research (Nov. 8, 2011) [hereinafter DoD Directive].

arguing that national security interests require that soldiers not be permitted to opt-out of "treatment" with investigational products.[14]

The DoD's policies and practices violate fundamental tenets of medical ethics and expose countless service members to unknown and potentially serious health risks. These dangers are not illusory. An investigational drug that was administered pursuant to an informed consent waiver during the Gulf War has recently been correlated with serious adverse health effects that have debilitated over 174,000 service members.[15] This equates to more than one in four soldiers who fought during the war.[16] Despite the revelation, the military continues to mandate experimental use of medical products, and the informed consent waiver remains a strategic option for the DoD.

In addition to the health and bioethical concerns raised by widespread administration of experimental products and the failure to obtain informed consent, military law dictates that service members are legally obligated to submit to medical treatments deemed necessary for the good of the armed forces.[17] Pursuant to this authority, the DoD has mandated that soldiers take investigational medical substances as a requirement of service.[18] For the DoD, refusing "treatment" equates to disobeying an order, which can result in punitive measures that include a court-martial and dishonorable discharge from the military.[19]

Coupled with the threat of severe punitive measures, military hierarchy often compels soldiers to submit to experimental treatment in instances where they otherwise may not have provided consent.[20] Given the socio-economic

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[14] Doe v. Sullivan, 938 F.2d 1370, 1373 (D.C. Cir. 1991); *see also* Victor W. Sidel & Barry S. Levy, *Physician-Soldier: A Moral Dilemma?*, *in* 1 MILITARY MEDICAL ETHICS 293, 296 (Thomas E. Beam & Linette R. Sparacino eds., 2003).

[15] *See* RESEARCH ADVISORY COMM. ON GULF WAR VETERANS' ILLNESSES, GULF WAR ILLNESS AND THE HEALTH OF GULF WAR VETERANS: SCIENTIFIC FINDINGS AND RECOMMENDATIONS 7–10 (2008) [hereinafter GULF WAR ILLNESS REPORT]; *see also Justice Delayed: Acknowledging the Reality of Gulf War Illness*, 372 THE LANCET 1856, 1856 (2008) [hereinafter *Justice Delayed*].

[16] GULF WAR ILLNESS REPORT, *supra* note 15, at 4.

[17] Doe v. Rumsfeld, 341 F. Supp. 2d 1, 6 (D.D.C. 2004); United States v. Washington, 57 M.J. 394, 398 (C.A.A.F. 2002); *see also* Annas & Annas, *supra* note 6, at 291.

[18] *See, e.g.*, *Rumsfeld*, 341 F. Supp. 2d at 3.

[19] *See, e.g.*, *Washington*, 57 M.J. at 400.

[20] *See* COMM. TO SURVEY THE HEALTH EFFECTS OF MUSTARD GAS & LEWISITE, INST. OF MED.,VETERANS AT RISK: THE HEALTH EFFECTS OF MUSTARD GAS AND LEWISITE, at v–x (Constance M. Pechura & David P. Rall eds., 1993) [hereinafter IOM REPORT]; MAXWELL J. MEHLMAN, THE PRICE OF PERFECTION: INDIVIDUALISM AND SOCIETY IN THE ERA OF BIOMEDICAL ENHANCEMENT 114 (2009); MORENO, *supra* note 8, at 134; Annas & Annas, *supra* note 6, at 308 ("It seems likely that most soldiers will volunteer . . . to take whatever their superior officers recommend."); Sidel & Levy, *supra* note 14, at 297 ("Because they cannot simply 'quit their jobs' or 'file a grievance' with a union, government agency, or professional organization, military personnel may not believe that they can truly refuse to participate in . . . experiments. They may feel more like a 'captive audience' than like

demographics of U.S. service members, current military medical policies and conventions arguably propagate discriminatory practices that are reminiscent of the four decades of illegal and unethical research conducted by the U.S. government during the Tuskegee syphilis experiments.[21] Studies have consistently found that the odds of a person entering the military are correlated with economic status, race, family structure, high school academic achievement, and parental education.[22] In this respect, and notwithstanding our current all-volunteer military, the societal implications of permitting an individual the ability to contract away their freedom are troubling.[23]

'volunteers.'"); Smith, *supra* note 1, at 518; Tennison & Moreno, *supra* note 8, at 2 (indicating that "[i]n the military context, the risk of coercion is much more pronounced").

[21] In 1932, the U.S. Public Health Service initiated an experiment in Alabama to study the course of untreated syphilis in poor, rural African-American males. *See* Allan M. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, 8 HASTINGS CENTER. REP., DEC. 1978, at 21, 21. The men were told that they were receiving free health care from the U.S. government. *See id.* at 24. To the contrary, over a forty-year period, the government conducted the "longest nontherapeutic experiment on human beings in medical history." Stephen B. Thomas & Sandra Crouse Quinn, *The Tuskegee Syphilis Study, 1932 to 1972: Implications for HIV Education and AIDS Risk Education Programs in the Black Community*, 81 AM. J. PUB. HEALTH 1498, 1498 (1991). Although penicillin became the preferred treatment for syphilis in the 1950s, the researchers did not provide any of the human subjects with the drug and prevented local doctors from doing so. *See* Brandt, *supra*, at 21. The research was the result of "extensive collaboration among government agencies" that included the U.S. Public Health Service, U.S. Centers for Disease Control, Alabama State Board of Health, Macon County Board of Health, and Macon County Medical Society, as well as local churches, public schools, and physicians. Thomas & Quinn, *supra*, at 1500; *see also* Brandt, *supra*, at 21, 25–26. As James Jones explains, "No scientific experiment inflicted more damage on the collective psyche of black Americans than the Tuskegee Study." JAMES H. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT 220 (1993).

[22] *See* Alair MacLean & Nicholas L. Parsons, *Unequal Risk: Combat Occupations in the Volunteer Military*, 53 SOC. PERSP. 347, 359–60 (2010).

[23] It is a fundamental tenet of classical liberal thought, commonly referred to as libertarianism, that the state should not interfere with the freedom of individuals to make their own choices. *See, e.g.*, Madison Powers, *Theories of Justice in the Context of Research*, *in* BEYOND CONSENT: SEEKING JUSTICE IN RESEARCH 147, 149 (Jeffrey P. Kahn, Anna C. Mastroianni, & Jeremy Sugarman eds., 1998) [hereinafter BEYOND CONSENT]. Examining the socio-economic elements of the military, placed in the context of the legal and regulatory framework for military medicine and research, serves as an engaging critique of libertarianism. As Madison Powers argues,

> [R]eliance on individual consent alone is not adequate to protect persons from exploitation under conditions of grossly unequal bargaining power, information, and human need. Under such conditions of inequality, some persons will bear greater burdens and receive fewer benefits of social cooperation. Justice therefore demands more than mere noninterference with voluntary agreements. Some role for government or other intervening institutions is needed to police such agreements and protect against exploitation.

Id. at 151–52.

Further troubling is the fact that, if experimental treatment or research harms a service member, sovereign immunity precludes the ability of the service member to seek legal remedies against the U.S. government.[24] Under the *Feres* doctrine, service members are precluded from raising tort claims against the government, government employees, or third-party contractors working in furtherance of governmental research if the underlying injury is sustained "in the course of activity incident to service" or relates to a discretionary function of military policy.[25] The United States Supreme Court has interpreted the *Feres* doctrine broadly to encompass claims that arise from experimental research, even in instances where the government covertly experimented on soldiers and intentionally disregarded legal requirements and informed consent protocols.[26]

The purpose of this Article is not to challenge the legitimacy of the government's justification for engaging in experimental research. Research that furthers national security interests is not inherently unethical or unjustifiable. Rather, the goal of this Article is to examine the history of military medicine and research and propose amendments to the legal and regulatory regime. Given the military's emphasis on human enhancement and biomedical innovations, a reevaluation of the underlying legal and regulatory framework is both timely and prudent, particularly since the U.S. Department of Health and Human Services (HHS) is currently considering amendments to the federal requirements for human-subjects research.[27]

The DoD has explicitly highlighted the importance of critically examining military medical ethics and has acknowledged that such debate "could challenge even our most basic presuppositions and that these challenges would cause discomfort."[28] My primary goal is to contribute to the ongoing dialogue.

With these considerations in mind, this Article proceeds as follows. Part II highlights past and current research projects of the U.S. military, while Part III outlines the legal, ethical, and regulatory framework governing military medicine and research. Part IV discusses race and class dynamics of the armed

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[24] United States v. Stanley, 483 U.S. 669, 684 (1987); *see also* MEHLMAN, *supra* note 20, at 213–14.

[25] Stencel Aero Eng'g Corp. v. United States, 431 U.S. 666, 672–74 (1977); Feres v. United States, 340 U.S. 135, 146 (1950).

[26] *Stanley*, 483 U.S. at 684.

[27] Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44512, 44512 (July 26, 2011) [hereinafter HHS Advance Notice of Proposed Rulemaking].

[28] Thomas E. Beam & Linette R. Sparacino, *Editors' Note* to Victor W. Sidel & Barry S. Levy, *Physician Soldier: A Moral Dilemma?*, *in* 1 MILITARY MEDICAL ETHICS 295 (2003). This position reflects Henry Beecher's observation in his classic article, *Experimentation in Man*: "Experimentation in man for scientific purposes is as old as recorded history. The need for constant examination of the procedure is equally ancient. This is required by progress in science and by the advance of ethical and moral concepts." Henry K. Beecher, *Experimentation in Man*, 169 JAMA 461, 461 (1959).

forces and the evolution of socio-economic trends. Part V sets forth the proposed reforms, which include amendments to the regulatory framework governing human-subjects research and investigational use of medical products, comprehensive medical monitoring and post-research medical treatment in instances of experimental use, and statutory exemptions to sovereign immunity. The driving force behind the proposed reforms is the desire to create a framework for military medicine and research that harmonizes national security interests with fundamental principles of patient autonomy and human dignity that ought apply, without exception, to all individuals.

II. EXPERIMENTAL RESEARCH AND THE U.S. MILITARY

For over a century the U.S. military has conducted and sponsored cutting-edge medical and technological research. Today, the military runs the "largest research program on biomedical enhancements."[29] Many of the resulting products have revolutionized daily life for both military and civilian populations. For example, DARPA-funded research has resulted in the creation of the Internet (initially called the Darpanet) and the computer mouse, while military physicians and researchers have made significant contributions to the study of infectious diseases and psychiatry.[30]

The Army Medical School, which was founded in 1893, is widely recognized as "the oldest school of public health and preventative medicine in the United States."[31] Currently called the Walter Reed Army Institute of Research, it spearheads countless research projects with collaborators from both

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[29] MEHLMAN, *supra* note 20, at 19.

[30] *See* MORENO, *supra* note 8, at 12; *see also* U.S. Army Med. Research & Material Command, *WRAIR Research and Development,* WALTER REED ARMY INST. OF RESEARCH, http://wrair-www.army.mil/WRAIRResearchandDevelopment.aspx (last modified Aug. 15, 2012). DARPA-funded research has also resulted in the creation of the Stealth Fighter and unmanned aerial vehicles (drone fighters). *See* MORENO, *supra* note 8, at 12. For reasons that are not difficult to discern, a significant number of research projects conducted by the DoD, DARPA, and American intelligence agencies are classified. *See id.* at 14. DARPA funds approximately $3 billion in research per year, about 90% of which supports university research. *Id.* at 13. The DoD's annual research and development budget is about $68 billion, which does not include related national security research funded by the Pentagon that is pursuant to a secret budget estimated to be at least $6 billion per year. *Id.* at 14 (noting that these estimates are speculative). DARPA alone has funded research projects at over 350 universities, with the Massachusetts Institute of Technology (MIT) and Johns Hopkins University being two of the top recipients. *Id.* at 20. In 2003, MIT received about $500 million from the DoD, and Johns Hopkins received about $300 million. *Id.*

[31] U.S. Army Med. Research & Material Command, *About WRAIR,* WALTER REED ARMY INST. OF RESEARCH, http://wrair-www.army.mil/AboutWRAIR.aspx (last modified Oct. 18, 2012).

the public and private sectors.[32] As with all aspects of the military, some projects have proven to be more controversial than others.

At a time when the U.S. military is actively pursuing transformative biomedical and technological innovations, analyzing the history of misfeasance in military research informs contemporary discussion as to the extent to which legal and regulatory reforms are desirable. Towards this end, this Part explores the egregious conduct of military researchers in the mid-to-late twentieth century, evaluates investigational studies that have shadowed military medicine for the past two decades, and highlights military research related to biomedical enhancements.

A. *Brief History of Experimental Research in the U.S. Military*

One of the earliest examples of experimental research involving human subjects dates to 1900, when Army Major Walter Reed conducted a study to determine the method of transmission of yellow fever.[33] Reed's yellow fever research is laudable not only for its findings but also for its research methods.[34] Each volunteer provided Reed with "written consent after being informed about the risks of the study,"[35] and volunteers were offered compensation and medical care for research-related injuries.[36] A number of American soldiers refused to accept the compensation, indicating that their decision to volunteer was "solely in the interest of humanity and the cause of science."[37]

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[32] U.S. Army Med. Research & Material Command, *WRAIR Partnership and Collaborations,* WALTER REED ARMY INST. OF RESEARCH, http://wrair-www.army.mil/WRAIRPartnershipandCollaborations.aspx (last modified Oct. 18, 2012).

[33] *See* Amoroso & Wenger, *supra* note 4, at 568. As one author explains,

> At the close of the 19th century, yellow fever was a known and feared pestilence of the western hemisphere and the coastal regions of West Africa, for which no cause or effective treatment was known. Known often as "yellow jack" because of the yellow quarantine flags on ships, the disease terrorized populations and severely disrupted trade.

J. Gordon Frierson, *The Yellow Fever Vaccine: A History*, 83 YALE J. BIOLOGY & MED. 77, 77 (2010).

[34] *See* John R. Pierce, *"In the Interest of Humanity and the Cause of Science": The Yellow Fever Volunteers*, 168 MILITARY MED. 857, 857 (2003). Reed and his colleagues, who were stationed in Cuba, received permission from Spanish authorities to solicit volunteers from the local population. *Id.* at 858.

[35] Amoroso & Wenger, *supra* note 4, at 568.

[36] *See* Pierce, *supra* note 34, at 858. Volunteers were offered $100 in gold and another $100 if they became ill. *Id.* In the end, over thirty men, including sixteen American service members, volunteered for the study, twenty-two of whom developed yellow fever. *Id.* at 857–58. One of the lead researchers volunteered to be bitten by a mosquito and nearly died from the subsequent illness. *Id.* at 858. Despite an expected death rate of 20% to 40%, no volunteer died from yellow fever. *Id.* at 857.

[37] *Id.* at 858.

The extent to which other scientists followed Reed's research protocols is unclear.[38] Although Army regulations from 1925 required that experimental research be conducted only on volunteers, it is not known how widespread the practice of obtaining voluntary informed consent was during the first half of the twentieth century.[39] Notwithstanding, during the Nuremberg Doctors Trials, the U.S. military relied heavily on fundamental tenets of medical ethics in prosecuting German military officials. The U.S. military also played an integral role in drafting the Nuremberg Code, which, among other provisions, requires voluntary consent for experimental research.[40]

While the United States assisted in the prosecution of German researchers for unethical conduct during World War II, it failed to publicly disclose that, during the same time period and for decades thereafter, it had engaged in unethical, if not illegal, experimental research on American civilians and service members.[41] Four examples include studies related to mustard gas, nuclear weapons, biological warfare, and psychotropic drugs.[42]

The U.S. mustard gas experiments were conducted under the auspices of the White House Office of Scientific Research and Development as part of the government's chemical warfare research program.[43] Since animal studies could not answer the government's research questions, the military decided to turn to human subjects.[44] The thousands of soldiers used in the mustard gas experiments were part of a larger program whereby over 60,000 soldiers were used in chemical research.[45] Some experiments sought to determine whether

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[38] *See* Amoroso & Wenger, *supra* note 4, at 568.

[39] *See id.*

[40] *See* Paul Weindling, *The Origins of Informed Consent: The International Scientific Commission on Medical War Crimes, and the Nuremberg Code*, 75 BULL. HIST. MED. 37, 49–51 (2001).

[41] *See* IOM REPORT, *supra* note 20, at vii. In the 1940s and 1950s, articles in the academic and popular press "suggest[ed] some tension between the [American] words at Nuremberg and the practices in America." HUMAN RADIATION EXPERIMENTS REPORT, *supra* note 2, at 87. While this Article focuses on military medicine and research, examining experimentation on prisoners provides interesting parallels. *See, e.g.*, Lawrence O. Gostin, *Biomedical Research Involving Prisoners: Ethical Values and Legal Regulation*, 297 JAMA 737 (2007).

[42] For much of the twentieth century, the military focused on "ABC" weapons, which refer to atomic, biological, and chemical warfare. *See* JONATHAN D. MORENO, UNDUE RISK: SECRET STATE EXPERIMENTS ON HUMANS xiii (2000) [hereinafter MORENO, UNDUE RISK].

[43] *See* IOM REPORT, *supra* note 20, at v. Mustard gas, which was first used in combat by Germany during World War I, is a poisonous and odorless gas that not only affects those exposed to the chemical, but also remains active in the soil for several weeks. *See* Patrick Cockburn, *U.S. Navy Tested Mustard Gas on Its Own Sailors*, THE INDEPENDENT, Mar. 14, 1993, *available at* http://www.independent.co.uk/news/world/us-navy-tested-mustard-gas-on-its-own-sailors-in-1943-the-americans-used-humans-in-secret-experiments-patrick-cockburn-in-washington-reports-on-the-survivors-who-bear-the-scars-1497508.html.

[44] *See* MORENO, UNDUE RISK, *supra* note 42, at 410.

[45] *Id.* at 37.

race or skin complexion helped explain susceptibility to mustard gas.[46] In addition to race-based human experimentation, the military tested prophylactic ointments and sought to create gas masks and protective clothing.[47]

During the experiments, some soldiers were exposed to gas levels equivalent to those reported on World War I battlefields.[48] The military also employed what they called "man-break" tests whereby researchers placed service members in gas chambers and released mustard gas to determine how long it would take for the men to become incapacitated.[49] Officers working on the mustard gas experiments recruited soldiers under false pretenses—when the soldiers would report for duty, officers would order the soldiers into gas chambers.[50] A Naval Research Laboratory report noted that, for soldiers who "did not cooperate fully," an "explanatory talk, and, if necessary, a slight verbal dressing down ha[d] always prove[d] successful."[51] Commanding officers threatened some soldiers with sanctions that included "immediate court martial and 40 years in prison."[52] Approximately 2,500 service members were used in the "man-break" tests.[53]

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[46] Smith, *supra* note 1, at 517. The studies were conducted at various locations, including the University of Chicago and Cornell University Medical College. *Id.* at 519. Researchers at Cornell believed that non-whites had "thicker skin" which may make them less sensitive to mustard gas. *Id.; see also* Marion B. Sulzberger et al., *Skin Sensitization to Vesicant Agents of Chemical Warfare*, 8 J. INVESTIGATIVE DERMATOLOGY 365, 372 (1947).

[47] *See* IOM REPORT, *supra* note 20, at v. Some tests had soldiers stand in a field, wearing various levels of protective clothing, as low-flying airplanes sprayed the men with mustard gas. *See* Smith, *supra* note 1, at 518.

[48] *See* IOM REPORT, *supra* note 20, at vii.

[49] Smith, *supra* note 1, at 518; MORENO, UNDUE RISK, *supra* note 42, at 37.

[50] *See* Cockburn, *supra* note 43. The experience of seventeen-year-old Nathan Schnurman, who was asked by military officials to test summer uniforms for the Navy, is telling:

> [Schnurman] was taken to a small army encampment called Edgewood in Maryland, where he was issued with a gas mask and told that the experiment was really about how well navy equipment resisted poison gas.
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> He was locked in a small hut heated by a furnace with a door that could be opened only from the outside. "I looked up at the ceiling and saw dark yellow oily mist rolling in." When something went wrong with his mask, he asked over the intercom to come out, but was refused. He vomited into his mask, passed out and had a heart attack, coming to later discover that somebody had dragged him into the fresh air.

Id.

[51] MORENO, UNDUE RISK, *supra* note 42, at 48 (internal quotation marks omitted). As the report further indicates, "There has not been a single instance in which a man has refused to enter the gas chamber." *Id.* at 48.

[52] Cockburn, *supra* note 43.

[53] *Id.*

As their name suggests, the "man-break" tests were grueling and resulted in severe research-related injuries, sometimes even death.[54] Soldiers experienced "immediate and severe eye injuries" and "enormous, grotesque blisters and oozing sores" on their "face[s], hands, underarms, buttocks, and genitals."[55] Exposure to mustard gas also caused blindness, intense vomiting, internal and external bleeding, and damage to the lungs and respiratory system.[56] Many soldiers suffered long-term health effects that included cancer, asthma, and psychological disorders.[57] Coupled with their research-related injuries, soldiers were told by their superiors that they would be prosecuted under the Espionage Act if they disclosed the true reason for their ailments.[58] This led to misdiagnoses and insufficient medical care.[59]

For decades, the government refused to acknowledge the existence of the studies or provide injured service members with compensation or long-term health care.[60] It was not until 1991 that officials formally admitted the use of soldiers in the research.[61] The government also admitted that it did not fully disclose safety risks or obtain informed consent from its subjects and that service members may have suffered adverse health effects as a result of their participation in the studies.[62]

Following the government's admissions, the U.S. Department of Veterans Affairs (VA) asked the Institute of Medicine (IOM) to conduct an investigation of the mustard gas experiments. During its investigation, the IOM found that "an atmosphere of lingering secrecy still existed in the Department of Defense," including "a picture of abuse and neglect that was impossible for the committee to ignore."[63]

Contemporaneous with the mustard gas experiments, the U.S. military conducted radiation experiments on American soldiers and civilians.[64] Researchers working on the Manhattan Project in 1942 understood that exposure to radiation was likely to be quite dangerous, even though "the deleterious effects of radiation could not be seen or felt and the results of over-exposure might not become apparent for long periods after such exposure."[65] In

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[54] *See* MORENO, UNDUE RISK, *supra* note 42, at 38–39.

[55] *See* Smith, *supra* note 1, at 518.

[56] *Id.*

[57] *See id.*; *see also* IOM REPORT, *supra* note 20, at vii.

[58] *See* Cockburn, *supra* note 43.

[59] *See id.*

[60] *See id.*

[61] *See* IOM REPORT, *supra* note 20, at v.

[62] *See id.* at v–vi. In turn, the government offered compensation and medical treatment for research-related injuries. *Id.* at 2.

[63] *Id.* at vi–vii. As Cockburn observes, "The bitterness of the veterans who were used as guinea pigs . . . stems from the refusal of the armed forces to acknowledge what had happened to them." Cockburn, *supra* note 43.

[64] *See* HUMAN RADIATION EXPERIMENTS REPORT, *supra* note 2, at 14–15.

[65] *Id.* at 6.

fact, one government researcher stated in 1943 that "[n]ever before has so large a collection of individuals been exposed to so much radiation."[66] Meanwhile, the military emphasized that "[w]ord of death or toxic hazard could leak out to the surrounding community and blow the project's cover."[67]

In 1951, after years of detonating atomic weapons in the South Pacific, the military began open-air testing of nuclear weapons in Nevada and other locations within the borders of the United States.[68] In addition to testing the effectiveness of the weapons, the government sought to understand the impact of nuclear warfare on humans, animals, and the environment.[69] The tests, which continued for more than a decade and were sanctioned by the U.S. Atomic Energy Commission (AEC),[70] also sought to uncover the "psychological effects of simulated nuclear combat" on service members.[71] Thousands of soldiers were placed in the immediate vicinity of atomic detonations without protective clothing. The military did not inform the soldiers of potential health risks, or seek to obtain informed consent prior to participation in the trials. First-hand accounts reveal that "soldiers with their eyes shut could see the bones in their forearms at the moment of explosion."[72]

Coupled with the land experiments, pilots were ordered to swallow film capsules and fly directly into radioactive clouds within minutes after detonation of a nuclear bomb.[73] Although the AEC had an exposure limit of 3.9 roentgens, the agency permitted exposure levels of twenty-five roentgens for the air experiments.[74] In the end, the researchers concluded that radiation exposure inside the human body was equivalent to radiation exposure outside the human body, a finding that confirmed results from earlier studies that used drone flights and mice.[75]

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[66] *Id.*

[67] *Id.*

[68] *See* Howard Ball, *Downwind from the Bomb*, N.Y. TIMES MAG., Feb. 9, 1986, at 33–34. Approximately one hundred atomic detonations occurred on U.S. soil during the 1950s. *Id.*

[69] *See* Leonard W. Schroeter, *Human Experimentation, the Hanford Nuclear Site, and Judgment at Nuremberg*, 31 GONZ. L. REV. 147, 213 (1996).

[70] The Atomic Energy Commission (AEC), which was established in 1946, inherited a number of atomic laboratories (including Los Alamos) that were used by the Army during World War II. *See* Margaret W. Rossiter, *Science and Public Policy Since World War II*, 1 OSIRIS 2D 273, 277 (1985).

[71] Ball, *supra* note 68, at 34–35. In 1951, the chair of the top medical advisory board for the U.S. Secretary of Defense urged the use of soldiers in radiation experiments "so they might overcome fear of radiation." Amoroso & Wenger, *supra* note 4, at 569.

[72] David Saul Schwartz, *Making Intramilitary Tort Law More Civil: A Proposed Reform of the* Feres *Doctrine*, 95 YALE L.J. 992, 994 n.16 (1986) (discussing first-hand accounts of soldiers exposed to atomic detonations).

[73] *See* Amoroso & Wenger, *supra* note 4, at 569.

[74] *Id.*

[75] *See id.*

Internal documents demonstrate that the AEC concluded that a causal relationship existed between radiation exposure and adverse health effects, yet the AEC publicly denied any potential harm to humans, plants, or animals.[76] At the same time, however, the government warned film manufacturers that atomic fallout could damage their products.[77] Despite the health and environmental hazards, the commissioner of the AEC privately asserted that "[w]e must not let anything interfere with this series of tests—nothing."[78] It was later uncovered that radiation exposure at the test sites was comparable to that of Hiroshima and Nagasaki.[79]

The radiation experiments were not limited to testing on service members, and civilian tests were no less disturbing than those on military personnel.[80] In collaboration with a number of well-respected universities, including the University of Chicago and the University of California, researchers injected unsuspecting civilians with radioactive elements that included plutonium, uranium, and polonium.[81] This research continued through the 1970s, with the government funding numerous projects that collected data from irradiated individuals.[82] In one government-sponsored experiment, school children were fed cereal laced with radioactive elements to study the pathway of the elements

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[76] *See* Ball, *supra* note 68, at 40. Although close to 25% of sheep herds in southern Utah and Nevada died shortly after the first bombs were detonated, the AEC attributed the deaths to "unprecedented cold weather." *Id.* at 38. When local newspapers began to question the potential health risks, the AEC responded that "the levels of radiation produced outside the test control area were in no way harmful to humans, animals or crops." *Id.* at 40. One woman's first-hand account is both telling and alarming. Gloria Gregerson, who testified in a Senate committee hearing in 1982, indicated that the fallout from the nuclear bombs "was so thick it was like snow. . . . We liked to play under the trees and shake the fallout onto our heads and our bodies, thinking that we were playing in the snow." *Id.* at 42. In 1958, Mrs. Gregerson was diagnosed with ovarian cancer, and she later contracted cancer of the intestines, stomach, and skin. *Id.* She died in 1983 at the age of forty-two. *Id.*

[77] MORENO, UNDUE RISK, *supra* note 42, at 9.

[78] Ball, *supra* note 68, at 41.

[79] *See* Schroeter, *supra* note 69, at 213.

[80] The government conducted experiments on prisoners, hospital patients, patients in mental institutions, and others "who did not have full faculties for informed consent." *Id.* at 157. In one study, researchers at MIT fed elderly patients radium and thorium, two radioactive elements that could have no benefit to the test subjects. *Id.* at 158. In another, over a period of eight years, researchers at the University of Washington Medical School x-rayed the testes of prisoners to examine the effects of ionizing radiation on human fertility and testicular function. *Id.* One civilian was experimented upon, without his knowledge or consent, after seeking emergency treatment in a hospital following a car accident. *See* MORENO, UNDUE RISK, *supra* note 42, at 120.

[81] *See* HUMAN RADIATION EXPERIMENTS REPORT, *supra* note 2, at 7, 145–46, 149–52, 154–55.

[82] *See id.* at 154–57.

in the human digestive system.[83] A congressional investigation in the 1980s found that "[n]o evidence was elicited that informed consent was granted in any of the cases," and that "[t]he government covered up the nature of the experiments and deceived the families of deceased victims."[84]

In the 1990s, the government acknowledged that hundreds of thousands of service members had been involved in at least 1,400 radiation projects over a thirty-year period after World War II.[85] Importantly, these figures do not include exposure suffered by civilians. As part of the civilian studies, the military conducted hundreds of "intentional radiation releases," whereby it deliberately emitted radioactive substances into densely populated cities and other locations to test human response and environmental contamination.[86] Although the government was aware that the radiation releases were likely to contaminate food and water supplies, many of the releases "took place with no public awareness or understanding."[87] Ten years after the commencement of the detonations on American soil, childhood leukemia deaths and diagnoses, as well as adult cancer deaths and diagnoses, were exponentially higher in Utah and

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[83] *See id.* at 196. The research was conducted in the 1950s at MIT, in conjunction with the Quaker Oats cereal company. *See id.* The parents of the children had given permission for the young boys to be in a "special club at the state school for children who were supposed to be 'mentally retarded.'" MORENO, UNDUE RISK, *supra* note 42, at 10. No mention was made of the experiments, and in 1997, MIT and Quaker Oats agreed to a civil settlement for $1.85 million. *See id.*

[84] Schroeter, *supra* note 69, at 157–58. When lab results disclosed radiation-related health injuries, the military decided to withhold the findings from the test subjects, expressing fear that litigation may ultimately result if the information were disclosed. *See* HUMAN RADIATION EXPERIMENTS REPORT, *supra* note 2, at 49. The government also aggressively defended its actions against plaintiffs who sought compensation for their injuries, relying heavily on governmental immunity as a basis for dismissing such claims. *Id.* A memorandum published in 1994 revealed that, over a recent three-year period, the government paid private law firms approximately $50 million to defend contractors against lawsuits brought by individuals who claimed to have been harmed by the radiation experiments. Keith Schneider, *U.S. Details Fees Paid to Fight Radiation Suits*, N.Y. TIMES, Jan. 4, 1994, at A10. The government also agreed to indemnify the contractors who participated in the experiments. *Id.*

[85] Schroeter, *supra* note 69, at 152.

[86] *See* HUMAN RADIATION EXPERIMENTS REPORT, *supra* note 2, at 317–53. Initially, in 1986, the government disclosed the existence of one radiation release—in Hanford, Washington in December 1949. *Id.* at 317. Following the Hanford intentional radiation release, "[l]ocal vegetation absorbed up to 400 times the then-permissible level of radiation, and animals about eighty times the standard safety limit." MORENO, UNDUE RISK, *supra* note 42, at 153. By 1993, the government reported twelve more intentional releases. *See* HUMAN RADIATION EXPERIMENTS REPORT, *supra* note 2, at 317. Three years later, the government admitted that hundreds of intentional releases were conducted between 1944 and the 1960s. *Id.*

[87] *Id.* at 318.

Nevada.[88] A National Cancer Institute report from 1997 concluded that radiation from atomic testing caused up to 75,000 thyroid cancers.[89]

Along with the radiation experiments, the U.S. military secretly conducted over 200 simulated biological warfare attacks on military and civilian populations.[90] Neither population consented to the tests, which occurred between 1949 and 1969.[91] According to one Congressman, the biological warfare program was "cloaked with greater secrecy than the nuclear weapons programs."[92]

In one instance, the military sprayed bacteria into the New York City subway to determine how far and fast bacteria could be transmitted.[93] Within minutes, the bacteria spread throughout the entire subway system.[94] Biological warfare tests also took place at National Airport in Washington, D.C.; Minneapolis, Minnesota; Oahu, Hawaii; and Saint Louis, Missouri.[95] In Alabama, pneumonia cases tripled shortly after biological warfare tests, while in 1957 and 1958 military cargo planes "crisscrossed the country" dispersing tons of chemical agents into the air.[96] Though some of the biological warfare tests were innocuous, others resulted in serious injuries.[97]

Coupled with the mustard gas, radiation, and biological warfare experiments, the U.S. military engaged in decades of classified research, beginning in the 1940s and continuing through the 1970s, to ascertain whether psychotropic drugs could be used effectively as chemical weapons or interrogation-facilitating agents.[98] The drugs included lysergic acid

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[88] *See* Ball, *supra* note 68, at 42.

[89] MORENO, UNDUE RISK, *supra* note 42, at 9.

[90] Elliott J. Schuchardt, *Walking a Thin Line: Distinguishing Between Research and Medical Practice During Operation Desert Storm*, 26 COLUM. J.L. & SOC. PROBS. 77, 98 (1992).

[91] *See id.*

[92] MORENO, UNDUE RISK, *supra* note 42, at 43.

[93] Schuchardt, *supra* note 90, at 99.

[94] *Id.*

[95] *See* MORENO, UNDUE RISK, *supra* note 42, at 233.

[96] *Id.* at 235–36.

[97] *See* Schuchardt, *supra* note 90, at 99. For example, over a six-day period in September 1950, the Army conducted a mock germ warfare exercise over San Francisco. *Id.* The Army contaminated 117 square miles with a form of bacteria that was believed to be harmless to humans. *Id.* Local hospitals later treated no less than eleven cases of infection caused by the bacteria. *Id.* The Army claimed the outbreak was "coincidental." *Id.*

[98] *See* Amoroso & Wenger, *supra* note 4, at 570. In 1953, only five years after the promulgation of the Nuremberg Code, Allen Dulles, the Director of the CIA, issued orders for secret experimentation (using LSD and other drugs) under the code name MKULTRA. *See* George J. Annas, *Mengele's Birthmark: The Nuremberg Code in United States Courts*, 7 J. CONTEMP. HEALTH L. & POL'Y 17, 36 (1991). In the 1970s, the CIA ordered that all records related to MKULTRA be destroyed. *Id.* at 37. Some documents survived the order, and thus information of the covert experiments came into the public limelight. *Id.*; *see also*

diethylamide (LSD), mescaline, marijuana, and over a dozen other drugs. These drugs were given to service members and civilians without their knowledge or consent.[99] Studies were conducted in military facilities and university medical centers, and many human subjects experienced serious adverse side effects.[100]

During the early stages of the research, the U.S. military recruited[101] Nazi scientists who had studied and participated in torture and brainwashing.[102] The recruitment of the German scientists for the psychotropic drug experiments was part of a larger program—dubbed Project Paperclip[103]—where more than 700 German researchers were brought to the United States to help further American research endeavors.[104]

Price, *supra* note 3, at 8–9 (discussing the CIA's programs to study mind control, brainwashing, interrogation, and torture).

[99] *See* Price, *supra* note 3, at 9.

[100] *See id.*

[101] The word "recruited" should be interpreted broadly. As John Gimbel explains, in some instances, Americans "evacuat[ed]" German scientists and their working groups. John Gimbel, *U.S. Policy and German Scientists: The Early Cold War*, 101 POL. SCI. Q. 433, 439–40 (1986). Seeking to leverage the expertise of German researchers for American endeavors—and fearful that the Russians would reach the scientists first—American operatives appeared in the homes of university professors and others at all hours of the day and night and informed the individuals that they had no more than twenty-four hours to pack their belongings. *Id.* at 439. As Gimbel notes, "They were asked to come voluntarily, but those who asked what would happen if they refused were told that force would be used or that they would be arrested." *Id.* The scientists could bring their families and "were promised jobs, housing, good living conditions, laboratory facilities, work contracts, and replacement of furniture, household utensils, and the personal property they had to leave behind." *Id.* at 440. Gimbel's observations are particularly noteworthy because he was a member of the occupation in Germany at the time and subsequently conducted approximately twenty years of research on the topic. *Id.* at 434.

[102] *See* John Gimbel, *German Scientists, United States Denazification Policy, and the 'Paperclip Conspiracy,'* 12 INT'L HIST. REV. 441, 441–42 (1990); Andrew Walker, *Project Paperclip: Dark side of the Moon*, BBC NEWS (Nov. 21, 2005), http://news.bbc.co.uk/2/hi/uk_news/magazine/4443934.stm. For example, Nazi researchers used concentration camp "prisoners to experiment with mescaline as a mind-control device." MORENO, UNDUE RISK, *supra* note 42, at 190–91.

[103] Project Paperclip "grew out of a highly secret wartime military operation code-named Project *Overcast* . . . [which] was a plan to bring to the United States about 350 German rocket scientists and engineers . . . 'to increase our war making capacity against Japan and aid our postwar military research.'" Gimbel, *supra* note 102, at 448. Project Overcast was approved in July 1945 and Project Paperclip in March 1946. *See id.*

[104] *See* Gimbel, *supra* note 102, at 441–42; Walker, *supra* note 102; *see also* David Cassidy, *Controlling German Science, I: U.S. and Allied Forces in Germany, 1945–1947*, 24 HIST. STUD. PHYSICAL & BIOLOGICAL SCI. 197, 197 (1994) (indicating that "German science figured prominently in U.S. and Allied plans before and during the occupation period"). The American government was also interested in proprietary research conducted by the Japanese, and at the conclusion of the war, the U.S. struck a deal with Japan to gain access to Japanese research data. *See* ADIL E. SHAMOO & DAVID B. RESNIK, RESPONSIBLE CONDUCT OF RESEARCH 241–42 (2d ed. 2009). From 1932 to 1945, Japanese researchers conducted

Although President Truman had issued an order that expressly excluded anyone who was "a member of the Nazi party" from aiding in U.S. projects,[105] the military "was intent on using Nazi specialists and was not about to let other government agencies or even a policy signed by President Truman get in its way."[106] Several of the Germans brought to the United States had been recently identified as war criminals, and the U.S. military falsified documents to conceal their true identities.[107] The military later justified its actions by arguing that national security interests far outweighed any legal or ethical concerns.[108]

Meanwhile, the psychotropic drug experiments continued for decades, on American soil and abroad, and thousands of soldiers suffered through the

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chemical and biological studies, most of which took place in China while it was under Japanese occupation. *Id.* at 241. A majority of the human subjects were people of Chinese ancestry and Allied prisoners of war. *Id.* In exchange for the data, the U.S. agreed not to prosecute the Japanese researchers for war crimes. *Id.* at 242. These atrocities were not widely known until the 1990s, and to this day, "Japanese political leaders have been reluctant to acknowledge that these crimes against humanity occurred." *Id.*

[105] *See* Walker, *supra* note 102.

[106] Gimbel, *supra* note 102, at 441 (quoting Linda Hunt, *U.S. Coverup of Nazi Scientists*, BULLETIN OF THE ATOMIC SCIENTISTS xli, 16–24). A number of commentators have suggested that, despite Truman's policy, Project Paperclip was "a national endeavor. Military officers were the project's most fervid sponsors, but its success depended on the support of Secretary of State James F. Byrnes, Under Secretary Dean Acheson, Secretary of Commerce Henry Wallace, F.B.I. Director J. Edgar Hoover, and President Harry S. Truman," among others. *Id.* at 442 (quoting CLARENCE G. LASBY, PROJECT PAPERCLIP: GERMAN SCIENTISTS AND THE COLD WAR 7–8 (1971)). According to Gimbel, "Project *Paperclip* was a national policy developed and implemented by duly authorized, responsible agents of the United States government, including several cabinet officers, who consulted with and obtained the approval of the president of the United States." *Id.* at 464.

[107] MORENO, UNDUE RISK, *supra* note 42, at 93–94; Gimbel, *supra* note 102, at 441–42; Walker, *supra* note 102. For example, some German scientists were classified by the American military as a "security risk," while others conducted experiments "at Dachau and Auschwitz, where inmates were frozen and put into low-pressure chambers, often dying in the process." *Id.* While war crimes and torture were insufficient reasons to reject a visa application of a German scientist, "'Communist affiliations or inclinations' was the only item identified specifically as 'a basis for unfavorable security evaluation.'" Gimbel, *supra* note 102, at 463 (quoting EUCOM, Intelligence Division, to JIOA, 7 May 1948, USNA RG 330, box 16, file theatre correspondence (Misc.)).

[108] *See* Gimbel, *supra* note 102, at 441–42. At the end of World War II, Major General Hugh Knerr, deputy commander of the U.S. Air Force in Europe, remarked:

> Occupation of German scientific and industrial establishments has revealed the fact that [the United States has] been alarmingly backward in many fields of research. If we do not take the opportunity to seize the apparatus and the brains that developed it and put the combination back to work promptly, we will remain several years behind while we attempt to cover a field already exploited.

Walker, *supra* note 102.

experiments without knowledge of their participation in the studies.[109] In one well-documented case, Army Master Sergeant James B. Stanley was repeatedly administered LSD in a military facility without his consent or knowledge.[110] Stanley had volunteered to participate in a program ostensibly designed to test the effectiveness of protective clothing and equipment as defenses against chemical warfare.[111] He met with researchers at a military base in Maryland four times a month, at which time he was secretly administered doses of LSD.[112] He later suffered from "hallucinations and periods of incoherence and memory loss" and "was impaired in his military performance."[113] Stanley would "awake from sleep at night and, without reason, violently beat his wife and children, later being unable to recall the entire incident."[114]

He was subsequently discharged from the army, his marriage dissolved, and his personal and professional life was ruined.[115] Nearly two decades after the experiments began, the Army sent Stanley a letter wherein it asked for his cooperation in a study of "the long-term effects of LSD on volunteers who participated in the 1958 tests."[116] This was the first time Stanley became aware that he was administered the drugs.[117]

Internally, the military justified the secret testing on "unwitting, non-volunteer Americans" by arguing that national security interests permit "a more tolerant interpretation of moral-ethical values, but not legal limits."[118] The military went on to argue that legal liability could be avoided by covering up the experiments.[119]

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[109] *See* MORENO, UNDUE RISK, *supra* note 42, at 250–54.

[110] United States v. Stanley, 483 U.S. 669, 671 (1987).

[111] *Id.*

[112] *Id.*

[113] *Id.*

[114] *Id.*

[115] *See id.*

[116] United States v. Stanley, 483 U.S. 669, 671 (1987) (internal quotation marks omitted).

[117] *Id.* at 672.

[118] *Id.* at 688 (Brennan, J., concurring in part and dissenting in part) (internal quotation marks omitted). Following a government investigation, CIA agents confessed to slipping LSD into the cocktails of unsuspecting civilians. MORENO, UNDUE RISK, *supra* note 42, at 189. In another case, military researchers spiked the drink of Dr. Frank Olson with LSD. *See id.* at 191. The drug led to a "psychiatric crisis," and he later "crashed through the window of his hotel room . . . and fell to his death." *Id.* Olson was a military researcher himself, and the CIA covered up his connection to the agency. *See id.* The lead researcher at the time, Dr. Sidney Gottlieb, "remained unrepentant" as to the experiments and Olson's death, "believing that the era justified his actions." *Id.* at 192.

[119] *Stanley*, 483 U.S. at 689 (Brennan, J., concurring in part and dissenting in part).

B. *Recent Experimental Research Projects*

While there is nothing to suggest that the U.S. military is currently supporting research that utilizes methods similar to those employed during the mustard gas, radiation, biological warfare, or psychotropic drug experiments, recent controversies have highlighted the military's efforts to mandate widespread use of medical products for off-label or investigational purposes and its emphasis on developing biotechnologies that seek to facilitate the cognitive and physical enhancement of service members. This subpart will focus on these two areas of research.

1. *Investigational and Off-Label Use of Medical Products*

Pursuant to statutory authority, the U.S. military has mandated that service members subject themselves to investigational and off-label use of medical products. While both off-label and investigational use involve utilization of a medical product for an indication that has not earned approval by the U.S. Food and Drug Administration (FDA),[120] there is a significant distinction between the two categories. For a product that is used off-label, the FDA has determined that the underlying product is safe and effective for at least one indication.[121] Investigational medical products, on the other hand, have not been found by the FDA to be safe and effective for any purpose. Widespread and nonconsensual use of off-label or investigational medical products raises a number of serious concerns. I will discuss four recent examples: pyridostigmine bromide (PB), the botulinum toxoid (BT) vaccine, the anthrax vaccine, and treatments for service-related mental health issues.

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[120] The FDA is charged with examining medical products for safety and efficacy, and determining whether the data reflect an acceptable risk-benefit profile for a given indication (also referred to as on-label use). *See* Robert J. Berlin, *Examination of the Relationship Between Oncology Drug Labeling Revision Frequency and FDA Product Categorization*, 99 AM. J. PUB. HEALTH 1693, 1693 (2009). Prior to approval, patients do not have a right to access investigational products, though regulatory guidelines permit compassionate use of medical products on a case-by-case basis and with the permission of the sponsor. 21 C.F.R. § 312.310 (2009). Post-approval, sponsors may only market their products for on-label indication(s), though physicians are free to prescribe approved products for off-label uses. *See* John E. Osborn, *Can I Tell You the Truth? A Comparative Perspective on Regulating Off-Label Scientific and Medical Information*, 10 YALE J. HEALTH POL'Y, L. & ETHICS 299, 303, 308 (2010). When a physician prescribes a drug for an off-label indication, the decision to do so must be based on an evaluation of a patient's particular health condition and risk factors and should only occur where medical data provides meaningful evidence that the potential benefits are likely to outweigh the known or expected risks and the patient provides informed consent to the treatment. *See, e.g.*, Weaver v. Reagen, 886 F.2d 194, 198 (8th Cir. 1989).

[121] Osborn, *supra* note 120, at 304.

In the early 1990s, fearing use of chemical weapons during the first Gulf War, the military sought to pretreat all service members with PB and the BT vaccine, two products that the FDA was evaluating for safety and efficacy as prophylactic medications aimed at mitigating the effects of chemical warfare.[122] Existing regulations did not grant the DoD with the ability to use investigational medical products without first obtaining informed consent. However, the DoD petitioned the FDA to establish a new rule that waives informed consent requirements for investigational use of medical products in times of existing or anticipated combat activities. The DoD was successful in its petition. Following the rule change, the FDA granted the DoD with permission to use PB and the BT vaccine pursuant to the new regulation.[123]

In its petition to the FDA, the DoD argued that it would not be feasible to obtain informed consent since a soldier's "personal preference" does not take precedence over the military's view that the drug and vaccine would contribute to the "safety of other personnel in a soldier's unit and the accomplishment of the combat mission."[124] The DoD also argued that "obtaining informed consent in the heat of imminent or ongoing combat would not be practicable."[125]

While the FDA granted the DoD's requests, the decision was not without controversy. The DoD claims that it believed the FDA had granted permission to use the products without informed consent because the FDA believed that the products were safe.[126] The FDA, on the other hand, claims that it granted the waiver because it believed that the DoD determined that military necessity required an informed consent waiver for investigational use of unapproved products.[127]

Regardless of the reason why the waiver was granted, as a condition of FDA permission to use investigational products without informed consent, the DoD agreed to: (1) provide information on PB to all service members; (2) collect, review, and make reports of adverse events related to PB; (3) label PB as an investigational product that was solely for "military use and evaluation"; (4) ensure that each dose of the BT vaccine was recorded in each service member's medical record; and (5) maintain adequate records related to the receipt, shipment, and disposition of the BT vaccine.[128] The DoD failed to comply with each of these requirements.[129]

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[122] Doe v. Sullivan, 938 F.2d 1370, 1372 (D.C. Cir. 1991); *see also* Protection of Human Subjects: Informed Consent, Exception from General Requirements, 64 Fed. Reg. 192, 54,188 (Oct. 5, 1999) [hereinafter FDA Interim Final Rule].

[123] *Sullivan*, 938 F.2d at 1374.

[124] *Id.* at 1373.

[125] *Id.*

[126] *See* Annas & Annas, *supra* note 6, at 301–02.

[127] *See id.* at 302.

[128] FDA Interim Final Rule, *supra* note 122, at 54, 188–89.

[129] *See id.*

Following use of PB and the BT vaccine, service members began suffering from serious health problems that included cognitive difficulties, chronic headaches, widespread pain, skin rashes, respiratory and gastrointestinal problems, and other chronic abnormalities.[130] Gulf War veterans have been diagnosed with amyotrophic lateral sclerosis (ALS) at a rate much higher than that of the general population or veteran populations from other wars and have had children born with birth defects at an alarming rate.[131] Commonly referred to as Gulf War illness, the health problems affect over 174,000 Gulf War veterans, which amounts to more than twenty-five percent of the fighting force during the war.[132] Included in the list of factors that is most likely to be a contributing factor to Gulf War illness is PB.[133]

The military's use of medical products for unapproved indications continued after the Gulf War. In 1998, the DoD implemented the Anthrax Vaccine Immunization Program (AVIP), which mandated off-label use of an existing anthrax vaccine for service members deemed to be at risk for anthrax exposure.[134] Although the vaccine had gained FDA approval to protect against cutaneous anthrax, the military sought to use the vaccine as a pretreatment for

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[130] *See* GULF WAR ILLNESS REPORT, *supra* note 15, at 1–2.

[131] *See id.* at 6.

[132] *See id.* at 4.

[133] *See id.* at 10 ("The strongest and most consistent evidence from Gulf War epidemiologic studies indicates that use of pyridostigmine bromide (PB) pills and pesticides are significant risk factors for Gulf War illness."); *see also Justice Delayed*, *supra* note 15, at 1856. In 2003, more than two decades after use of PB by the U.S. military, the drug was approved for use in combat through the Bioterrorism Act's animal-efficacy standard. William J. FitzPatrick & Lee L. Zwanziger, *Defending Against Biochemical Warfare: Ethical Issues Involving the Coercive Use of Investigational Drugs and Biologics in the Military*, 3 J. PHIL., SCI. & L. (2003), https://www6.miami.edu/ethics/jpsl/archives/papers/drugs.html; *see infra* notes 299–303 and accompanying text (discussing the Bioterrorism Act and the animal-efficacy standard).

[134] H. COMM. ON GOV'T REFORM, THE DEPARTMENT OF DEFENSE ANTHRAX VACCINE IMMUNIZATION PROGRAM: UNPROVEN FORCE PROTECTION, H.R. REP. NO. 106-556, at 6–9 (2000) [hereinafter ANTHRAX VACCINE CONGRESSIONAL REPORT]. AVIP was created pursuant to a 1993 DoD policy that calls for "immunizations 'against validated biological warfare threat agents, for which *suitable* vaccines are available.'" *Id.* at 5 (emphasis added) (citing DEPARTMENT OF DEFENSE, DOD DIRECTIVE 6205.3, *DoD Immunization Program for Biological Warfare Defense* (1993)). Within months after implementation of AVIP, the sole producer of the anthrax vaccine was purchased by BioPort Corporation, which was a new company formed by private investors that included former Joint Chiefs Chairman Admiral William J. Crowe. *Id.* at 8. The following month, the DoD awarded the company with a $29 million no-bid contract, and less than one year later, the DoD increased the contract to $53.1 million and provided $18.7 million in advance payments. *Id.* The DoD also indemnified the company against liability for adverse reactions or the failure to confer immunity against anthrax. *Id.* at 8–9.

inhalation anthrax.[135] From the outset, the program caused considerable controversy.[136]

A 2000 congressional report criticized AVIP, characterizing the program as an "overwrought response to the threat of anthrax" and one that "compromises the practice of medicine to achieve military objectives."[137] The report found that the DoD provided service members with "[h]eavy handed, one-sided informational materials[,]" that the agency was "far more concerned with public relations than effective force protection or the practice of medicine[,]" and that pursuant to FDA regulations use of the vaccine for inhalation anthrax amounted to investigational use.[138] The committee recommended that the program be halted until the DoD obtains FDA approval for use of the vaccine as a pretreatment for inhalation anthrax.[139]

The DoD refused to suspend the program, and within the first two years of AVIP, no less than twenty-four service members were discharged "under other than honorable conditions" for refusing the anthrax vaccine.[140] By 2002, disciplinary action had been taken in well over 100 Air Force cases alone, including at least one Air Force physician who refused to be vaccinated.[141]

The few publicly available military court decisions from the anthrax cases provide significant insight into the DoD's legal justifications for mandating off-label use of the vaccine. DoD prosecutors repeatedly sought to exclude all evidence concerning the safety and efficacy of the anthrax vaccine, and military

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[135] Rempfer v. Sharfstein, 583 F.3d 860, 863–64 (D.C. Cir. 2009). Vaccine side effects include severe muscle aches and anaphylaxis, which can lead to death. ANTHRAX VACCINE CONGRESSIONAL REPORT, *supra* note 134, at 9.

[136] ANTHRAX VACCINE CONGRESSIONAL REPORT, *supra* note 134, at 1–2. Shortly after implementation of AVIP, the military encountered a supply shortage that resulted in a temporary suspension of the program. *Rempfer*, 583 F.3d at 863–64. Service members who had begun the six-dose schedule were forced to miss doses. *Id.* When the military regained a supply of the vaccine, it indicated that those service members who began the dosing schedule would not repeat doses but would continue with the next dose of the vaccine. *Id.* This was contrary to the label indication for the vaccine. *Id.* at 862.

[137] ANTHRAX VACCINE CONGRESSIONAL REPORT, *supra* note 134, at 2.

[138] *Id.* at 2–3. According to the report, the DoD's efforts fueled "suspicions the program understates adverse reaction risks in order to magnify the relative, admittedly marginal, benefits of the vaccine." *Id.* at 2.

[139] *Id.* at 4.

[140] MORENO, UNDUE RISK, *supra* note 42, at 269. One of the discharged service members later stated:

> [F]or you to believe the military would never do anything to hurt me, then I suggest you talk to the many sick Americans that returned from the Persian Gulf. I love this country and I am willing to die, but only in war. Not because they are experimenting on me.

Id.

[141] *See* Bates v. Rumsfeld, 271 F. Supp. 2d 54, 57–58 (D.D.C. 2004); United States v. Washington, 57 M.J. 394, 400 (C.A.A.F. 2002); Randall D. Katz, *Friendly Fire: The Mandatory Military Anthrax Vaccination Program*, 50 DUKE L.J. 1835, 1837 (2001).

judges consistently granted these motions.[142] Service members argued that the off-label use of the vaccine amounted to investigational use under FDA requirements, but military courts staunchly upheld AVIP, citing a DoD instruction that characterized the anthrax vaccine as "an FDA-licensed product and not an IND requiring informed consent for its administration."[143] The DoD instruction contradicted earlier positions taken by the agency wherein it "acknowledged tacitly" that use of the vaccine for inhalation anthrax constitutes investigational use.[144]

Despite a long line of losing efforts, service members continued to refuse the vaccine and challenge resulting military sanctions in court. In 2003, six service members filed a lawsuit seeking to enjoin the military from continuing AVIP since the military did not obtain informed consent prior to inoculations, nor did the DoD obtain a presidential waiver from the informed consent requirements.[145] A federal district court granted the injunction, finding that AVIP amounted to off-label use of a vaccine and that the DoD was obligated to comply with one of the two options regarding informed consent.[146]

Eight days after the injunction, the FDA approved the anthrax vaccine "independent of the route of exposure," which captured the indication of inhalation anthrax.[147] Upon further challenge by the service members, the court vacated the FDA's decision on procedural grounds because the agency did not adhere to regulations governing approval of the new indication.[148] Notably, the court rejected the DoD's arguments that a soldier's refusal to submit to the order to be inoculated with the anthrax vaccine would "undermine a key component of military readiness and defense" and that "requiring the DoD to obtain informed consent will interfere with the smooth functioning of the military."[149]

Thereafter, Congress stepped in to aid the DoD by enacting the Project BioShield Act of 2004, which authorizes the FDA with the ability to grant the DoD permission to use a medical product for off-label or investigational

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[142] *See, e.g.*, United States v. Johnson, No. NMCCA 200001433, 2004 WL 720153, at *1 (N-M. Ct. Crim. App. 2004); *Washington*, 57 M.J. at 396; Perry v. Wesely, No. NMCM 200001397, 2000 WL 1775249, at *1 (N-M. Ct. Crim. App. 2000); Ponder v. Stone, 54 M.J. 613, 614 (N-M. Ct. Crim. App. 2000).

[143] *Ponder*, 54 M.J. at 616–17; *see also* United States v. Schwartz, 61 M.J. 567, 571 (N-M. Ct. Crim. App. 2005); *Perry*, 2000 WL 1775249, at *3.

[144] Katz, *supra* note 141, at 1861.

[145] Doe v. Rumsfeld, 341 F. Supp. 2d 1, 3 (D.D.C. 2004).

[146] *Id.* at 6.

[147] *Id.*

[148] *See id.* at 13–16.

[149] Doe v. Rumsfeld, 297 F. Supp. 2d 119, 123, 134 (D.D.C. 2003). As the court indicated, "[A]bsent an informed consent or presidential waiver, the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." *Id.* at 135.

purposes during a declared emergency.[150] This law was then used to grant the DoD the ability to continue using the anthrax vaccine for unapproved indications, a move which trumped the court order.[151] During the time that the DoD was permitted to continue with AVIP pursuant to the emergency order, the FDA approved the vaccine regardless of the route of exposure.[152]

Although the service members again challenged the FDA's decision, the Court of Appeals for the D.C. Circuit dismissed the action because it found that the FDA did not act arbitrarily or capriciously in approving the new indication during the second review.[153] Since March 1998, over 2,300,000 service members have received the anthrax vaccine.[154] Although a next-generation anthrax vaccine has been a top priority for the military since the early 1990s—and despite over $1 billion in research since that time—a new vaccine has yet to earn FDA approval.[155]

Today, some of the most pressing medical issues facing service members include traumatic brain injury (TBI), post-traumatic stress disorder (PTSD), and other mental health issues.[156] Since 2001, approximately 2,600,000 U.S. soldiers have been deployed to Iraq and Afghanistan; 900,000 of whom have had more than one deployment.[157] A decade of intense fighting has resulted in a "substantial mental health burden for war veterans and their families."[158] Veterans of these wars have required mental health treatment for serious mental disorders much more than that seen in previous wars, suicide rates for enlisted

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[150] Pub. L. 108-276, § 4, 118 Stat. 835, 853 (2004).

[151] *See* Stuart L. Nightingale et al., *Emergency Use Authorization (EUA) to Enable Use of Needed Products in Civilian and Military Emergencies, United States*, 13 EMERGING INFECTIOUS DISEASES 1046, 1046 (July 2007). Despite an extensive review process, see *infra* notes 294–96 and accompanying text, the emergency order was granted within five weeks. *See* Nightingale et al., *supra*, at 1050. During the pendency of the emergency order, the DoD administered more than 100,000 anthrax vaccinations. *See id.*

[152] Rempfer v. Sharfstein, 583 F.3d 860, 864 (D.D.C. 2009).

[153] *Id.* at 868.

[154] *See Slide 1*, ANTHRAX VACCINE IMMUNIZATION PROGRAM (Sept. 14, 2009), http://search.anthrax.mil/anthrax/query.html?col=atx&ht=0&qp=&qt=Anthrax+Vaccine+Facts&qs=&qc=&pw=100%25&ws=0&la=en&qm=0&st=1&nh=10&lk=1&rf=0&rq=0&si=1&x=59&y=6 (located at slide 17).

[155] *See* KENDALL HOYT, LONG SHOT: VACCINES FOR NATIONAL DEFENSE 1 (2012). In this respect, it is worthwhile to explore whether off-label use and informed consent waivers disincentivize innovation.

[156] *See* COMM. ON THE ASSESSMENT OF ONGOING EFFORTS IN THE TREATMENT OF POSTTRAUMATIC STRESS DISORDER, INST. OF MED., TREATMENT FOR POSTTRAUMATIC STRESS DISORDER IN MILITARY AND VETERAN POPULATIONS: INITIAL ASSESSMENT 1 (2012) [hereinafter IOM REPORT ON PTSD]; Charles W. Hoge, *Interventions for War-Related Posttraumatic Stress Disorder*, 306 JAMA 549, 549 (2011).

[157] *See* IOM REPORT ON PTSD, *supra* note 156, at 17.

[158] Hoge, *supra* note 156, at 549.

service members and veterans are at an all-time high, and barriers to care have been well documented.[159]

Because of improved protective equipment, a higher percentage of soldiers are surviving injuries that would have been fatal in previous wars.[160] At the same time, head and neck injuries have been reported in twenty-five percent of soldiers who have been evacuated from Iraq and Afghanistan.[161] Blast-related TBI has been labeled the signature injury of the wars.[162]

Soldiers with TBI have reported post-concussive symptoms that include irritability, memory problems, headache, and difficulty concentrating.[163] In response, the DoD and the VA have implemented new screening procedures for TBI.[164] Despite these efforts, the measures adopted by the agencies are "inadequate for achieving the objectives of these well-intentioned initiatives."[165] The VA's failure to adequately treat veterans with mental health issues has had a devastating effect on veteran health and morale.[166] Moreover, a recent Inspector General report found that the VA has been entering false data into its computer system so as to cover up its failure to timely and adequately provide mental health care for veterans.[167] Shockingly, this was the third such finding since 2005.[168] As one veteran observed, "this suggests a systematic misrepresentation of data and an unwillingness to stop it."[169]

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[159] *See* Annas & Annas, *supra* note 6, at 304; Edward A. Selby et al., *Overcoming the Fear of Lethal Injury: Evaluating Suicidal Behavior in the Military Through the Lens of the Interpersonal-Psychological Theory of Suicide*, 30 CLINICAL PSYCHOL. REV. 298, 299–300 (2010); IOM REPORT ON PTSD, *supra* note 156, at 12, 339–56.

[160] *See* Charles W. Hoge et al., *Mild Traumatic Brain Injury in U.S. Soldiers Returning from Iraq*, 358 NEW ENG. J. MED. 453, 454 (2008).

[161] *See id.*

[162] *See id.*

[163] *See id.* One recent study presented preliminary findings that linked blast-related injuries to neurodegeneration. *See generally* Lee E. Goldstein et al., *Chronic Traumatic Encephalopathy in Blast-Exposed Military Veterans and a Blast Neurotrauma Mouse Model*, 4 SCI. TRANSLATIONAL MED. 134, May 16, 2012, at 1 (discussing the study and its findings).

[164] *See* Hoge et al., *supra* note 160, at 454.

[165] Charles W. Hoge, Herb M. Goldberg & Carl A. Castro, *Care of War Veterans with Mild Traumatic Brain Injury—Flawed Perspectives*, 360 NEW ENG. J. MED. 1588, 1588 (2009).

[166] *See* Mike Scotti, Op-Ed., *The V.A.'s Shameful Betrayal*, N.Y. TIMES, May 28, 2012, at A17.

[167] *See id.* VA protocols call for a full mental health evaluation within fourteen days of an initial screening. *See id.* Although VA records reflect an attainment rate of 95%, once the false entries were removed, the rate dropped to 49%, and the actual average wait was fifty days. *See id.* For soldiers with serious mental health concerns, particularly those who are contemplating suicide, each day makes a "difference between life and death." *Id.*

[168] *See id.*

[169] *Id.*

Military physicians face increased difficulty in diagnosing and treating patients with TBI because many symptoms overlap with dissociative symptoms of acute stress disorder, PTSD, and other disorders.[170] While hundreds of thousands of soldiers have experienced TBI, the majority of episodes have gone untreated.[171] Little is known about the long-term adverse effects of TBI,[172] and the subjective nature of diagnosis complicates screening and treatment efforts.[173]

Complicating the predicament is the VA's recently created disability category called "residuals of TBI."[174] This category assigns a forty percent "disability to persons who have three or more subjective symptoms that 'moderately' interfere with functioning or who have 'objective evidence' of 'mild impairment of memory, attention, concentration, or executive functioning resulting in mild functional impairment.'"[175] According to one report, this disability category "ignores extensive literature demonstrating the strong association between compensation and persistence of symptoms after concussion."[176]

From the perspective of the military physician, the TBI disability category clouds treatment strategies and complicates evidence-based treatments for TBI and related disorders.[177] Consequences include adverse side effects from medications and inappropriate treatment, use of unproven rehabilitation procedures, prescribing of medications for unapproved indications, use of unproductive, costly, and time-consuming tests, and the failure to address underlying conditions such as depression, PTSD, or substance abuse.[178]

In addition, treatment for depression, PTSD, and anxiety disorders has increasingly utilized newer psychotropic medications, particularly selective serotonin-reuptake inhibitors (SSRIs).[179] PTSD has been strongly associated with TBI,[180] and soldiers with TBI have reported significantly higher rates of other physical and mental health problems.[181] As a result, military psychiatrists have recommended that physicians in war zones have SSRIs "in large quantities, to be used for both depressive disorders and anxiety disorders."[182]

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[170] *See* Hoge et al., *supra* note 160, at 454.

[171] *See* Hoge, Goldberg & Castro, *supra* note 165, at 1588.

[172] *See* Christine L. Mac Donald et al., *Detection of Blast-Related Traumatic Brain Injury in U.S. Military Personnel*, 364 NEW ENG. J. MED. 2091, 2092 (2011).

[173] *See* Hoge, Goldberg & Castro, *supra* note 165, at 1589.

[174] *Id.* at 1590.

[175] *Id.*

[176] *Id.*

[177] *See id.* at 1591.

[178] *See id.*

[179] *See* Annas & Annas, *supra* note 6, at 304.

[180] *See* Hoge et al., *supra* note 160, at 457; Mac Donald et al., *supra* note 172, at 2099.

[181] *See* Hoge et al., *supra* note 160, at 459.

[182] Annas & Annas, *supra* note 6, at 304 (citing Benedek et al., *Psychiatric Medications for Deployment: An Update*, 172 MIL. MED. 681, 683 (2007)).

Despite these recommendations, a number of studies have questioned the safety and efficacy of SSRIs.[183] Off-label use of SSRIs is particularly troubling, with some studies finding long-term adverse health effects and no meaningful clinical benefit.[184] Today, SSRIs have been described as "the new villains of modern psychopharmacology—overhyped, overprescribed chemicals," while "the very theory for how these drugs work has been called into question."[185] Furthermore, a number of medications that are commonly used to augment treatment with SSRIs "have generally been disappointing."[186]

For example, benzodiazepines[187] are "widely prescribed" medications despite the fact that studies have found that the drugs "are relatively contraindicated and should be discouraged."[188] Benzodiazepines have been found to lead to drug dependence "and can become almost impossible to discontinue in combat veterans due to rebound exacerbation of symptoms . . . ."[189]

In addition to use of benzodiazepines, "off-label use of second-generation (atypical) antipsychotics has gained wide popularity, particularly quetiapine and risperidone."[190] This is equally as troubling because "there are numerous concerns with long-term adverse health effects."[191] Coupled with an increased risk of adverse health effects, the largest randomized control trial (as of August 2011) found no meaningful clinical benefit in the risperidone group when compared to the placebo group.[192]

These studies cast serious doubt over the off-label use of medications for service members with mental health issues. According to many scientists, focusing treatment on chemical imbalances in brain chemistry is "last-century thinking."[193] Yet, decades of characterizing depression and other mental health

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[183] *See, e.g.*, Hoge, *supra* note 156, at 550; *see generally* IRVING KIRSCH, THE EMPEROR'S NEW DRUGS: EXPLODING THE ANTIDEPRESSANT MYTH (2010) (reviewing a number of studies critical of SSRIs); Marcia Angell, *The Epidemic of Mental Illness: Why?*, N.Y. REV. BOOKS, June 23, 2011; Marcia Angell, *The Illusions of Psychiatry*, N.Y. REV. BOOKS, July 14, 2011.

[184] *See, e.g.*, KIRSCH, *supra* note 183; Hoge, *supra* note 156, at 550; Angell, *The Epidemic of Mental Illness: Why?*, *supra* note 183; Angell, *The Illusions of Psychiatry*, *supra* note 183.

[185] *See, e.g.*, Siddhartha Mukherjee, *Post-Prozac Nation*, N.Y. TIMES, Apr. 19, 2012 (Magazine), http://www.nytimes.com/2012/04/22/magazine/the-science-and-history-of-treating-depression.html?pagewanted=all.

[186] Hoge, *supra* note 156, at 550.

[187] Benzodiazepines include Xanax, Ativan, and Valium.

[188] Hoge, *supra* note 156, at 550.

[189] *Id.*

[190] *Id.*

[191] *Id.*

[192] *See id.*

[193] Alix Spiegel, *When It Comes to Depression, Serotonin Isn't the Whole Story*, NPR NEWS HEALTH BLOG (Jan. 23, 2012, 12:01 AM), http://www.npr.org/blogs/health/2012/01/

disorders as biological or chemical "has convinced many people to take antidepressants" in circumstances where other treatments can work just as well, if not better.[194]

Reports have consistently highlighted the dangers of off-label prescribing, particularly for mental health conditions and where off-label use is not based on a comprehensive clinical evaluation.[195] Since off-label uses have not been evaluated by the FDA, service members cannot be certain that they are receiving accurate risk-benefit profiles and thus arguably are unable to make informed decisions as to treatment options.[196] Taken together, investigational and off-label uses of medical products place service members at a heightened risk for both short-term and long-term health problems.

2. *Physical and Cognitive Enhancement of Service Members*

The fundamental goal of military training is to enhance service members—to make them smarter, stronger, and more able fighters. Increasingly, enhancement techniques have sought to leverage innovative medical products and technologies. As the director of DARPA explains, the agency's goal is to "exploit the life sciences to make the individual warfighter stronger, more alert, more endurant, and better able to heal."[197] Given modern warfighting

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23/145525853/when-it-comes-to-depression-serotonin-isnt-the-whole-story. While serotonin plays a role in depression, low serotonin is not likely to be the cause of depression. *See id.*

[194] *Id.*

[195] *See* IOM REPORT ON PTSD, *supra* note 156, at 232 (discussing the lack of evidence-based support for PTSD treatments); *see also* Bruce M. Psaty & Wayne Ray, *FDA Guidance on Off-Label Promotion and the State of the Literature from Sponsors*, 299 JAMA 1949, 1949 (2008) (finding that of the 160 most commonly prescribed medications, seventy-three percent of "off-label uses had little or no scientific support").

[196] Off-label use of any medical product is proper only if administration is part of an overall treatment plan, is medically indicated, and is provided with the voluntary and informed consent of the service member. *See* George J. Annas, *Globalized Clinical Trials and Informed Consent*, 360 NEW ENG. J. MED. 2050, 2052 (2009). Forced off-label or investigational use of medical products at the population level is distinguishable from forced on-label uses. For example, public schools require childhood vaccinations as a condition of enrollment. *See, e.g.*, Anthony Ciolli, *Religious and Philosophical Exemptions to Mandatory School Vaccinations: Who Should Bear the Costs to Society?*, 74 MO. L. REV. 287, 287 (2009). In these instances, all requirements are to on-label uses of the vaccines, and all but two states have instituted religious or philosophical exemptions. *Id.* In the military context, forced on-label use of medical products is defensible on public health grounds, so long as the underlying product serves population-level health concerns.

[197] MORENO, *supra* note 8, at 11 (quoting Tony Tether, *Statement to the Subcommittee on Terrorism, Unconventional Threats and Capabilities*, Mar. 27, 2003, at 12, *available at* http://www.darpa.mil/WorkArea/DownloadAsset.aspx?id=1778) (internal quotation marks omitted).

capabilities, "the major limiting factor for operational dominance in a conflict is the warfighter."[198]

Such endeavors have raised a number of challenging questions.[199] Is there a valid distinction between "artificial" and "natural" enhancement?[200] Under what circumstances should enhancements that are under development be administered to service members? Ought medical enhancements ever be a required aspect of service in the military? Reflecting on these inquiries, this subpart examines the military's biomedical enhancement projects.

DARPA's "Persistence in Combat" program "aims to create soldiers who are 'unstoppable' because pain, wounds and bleeding are kept under their control."[201] This program includes research directed at developing a vaccine that will block intense pain within seconds, use of photobiomodulation to accelerate wound healing, and the creation of a chemical cascade to stop bleeding within minutes.[202] DARPA research has also explored the ability to genetically engineer the human immune system so that it could recognize and adapt to any pathogen.[203] As the agency explains, its goal is "to have almost superhuman beings whose own body will be able to defend itself."[204]

Through its "Metabolic Dominance" program, DARPA seeks to create a powerful nutraceutical—a pill with nutritional value that would vastly improve a soldier's endurance.[205] DARPA's vision is "to enable superior physical and physiological performance by controlling energy metabolism on demand. An example is continuous peak physical performance and cognitive function for

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[198] *Id.* at 117.

[199] As President George W. Bush's Council on Bioethics noted: "We might lose sight of the difference between real and false excellence, and eventually not care. And in the process, the very ends we desire might become divorced from any idea of what is humanly superior and therefore humanly worth seeking or admiring." PRESIDENT'S COUNCIL ON BIOETHICS, BEYOND THERAPY: BIOTECHNOLOGY AND THE PURSUIT OF HAPPINESS 155 (2003) [hereinafter PRESIDENT'S COUNCIL ON BIOETHICS].

[200] The dividing line between therapy and enhancement is, at best, ambiguous. *See, e.g.*, Paul Root Wolpe, *Treatment, Enhancement, and the Ethics of Neurotherapeutics*, 50 BRAIN & COGNITION 387, 388 (2002). Some bioethicists argue that all medical treatment should be deemed enhancement because such treatment involves altering the natural course of a human's life. *See, e.g.*, John Harris, *Enhancements Are a Moral Obligation*, *in* HUMAN ENHANCEMENT 131, 152–53 (Julian Savulescu & Nick Bostrom eds., 2009). Others draw the line at whether a biomedical product results in a characteristic that is beyond that typical of human traits. *See, e.g.*, Inmaculada de Melo-Martín, *Defending Human Enhancement Technologies: Unveiling Normativity*, 36 J. MED. ETHICS 483, 483–84 (2010). For a provocative compilation of essays on the topic of human enhancements, see HUMAN ENHANCEMENT, *supra*.

[201] Annas & Annas, *supra* note 6, at 286.

[202] *Id.*

[203] *See* MORENO, UNDUE RISK, *supra* note 42, at 291.

[204] *Id.*

[205] MORENO, *supra* note 8, at 121.

three to five days, twenty-four hours per day, without the need for calories."[206] DARPA-funded researchers are also developing bacteria that, once ingested, would "enable soldiers to obtain nutritional value from normally indigestible substances."[207]

In addition to enhancements that endeavor to minimize pain, accelerate wound healing, and limit the need for traditional food, DARPA is also researching ways to alter the body's core temperature.[208] If successful, soldiers with severe injuries would be able to go into hibernation while they healed, either through self-administration of medication or through the administration of medicine from a central command center via remote access to the injured soldier's combat suit.[209] As Jonathan Moreno explains, "[]regulating the body's internal heat[] will be here faster than people think."[210]

Coupled with these programs, "the security establishment's interest and investment in neuroscience, neuropharmacology . . . and related areas [is] extensive and growing."[211] The military began funding neuroscientific research in the 1960s, when the modern computer era began to take off.[212] Central to the Pentagon's early research endeavors were two laboratories at Stanford University.[213] In one lab, "scientists and engineers worked to replace the human mind," while in the other, "a similar group worked to augment it."[214] The goals were artificial intelligence and intelligence augmentation, two fields that have flourished over the past five decades.[215]

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[206] *Id.*

[207] MEHLMAN, *supra* note 20, at 19.

[208] *See* MORENO, *supra* note 8, at 122.

[209] *See id.*

[210] *Id.* (quoting Noah Shachtman, *DARPA Offers No Food for Thought*, WIRED, http://www.wired.com/medtech/health/news/2004/02/62297 (last visited Sept. 26, 2012) (statement of DARPA consultant)).

[211] *See id.* at 4; Tennison & Moreno, *supra* note 8, at 1.

[212] *See* John Markoff, *A Fight to Win the Future: Computers vs. Humans*, N.Y. TIMES, Feb. 15, 2011, at D1.

[213] *See id.*

[214] *Id.*

[215] *See id.* For example, IBM has recently developed a machine that "can understand questions posed in natural language and answer them." John Markoff, *Computer Wins on 'Jeopardy!': Trivial, It's Not*, N.Y. TIMES, Feb. 17, 2011, at A1. In addition, researchers at the University of Southern California have successfully used carbon nanotubes to build a functioning synapse which, they argue, is the first step to building a functioning synthetic brain. *See* Sue Halpern, *Mind Control & the Internet*, N.Y. REV. BOOKS, June 23, 2011, at 33. The DoD is also working with IBM on "cognitive computing" technologies. Oliver Renick, *IBM Chip 'Senses' Events to React in Ways that Mimic Human Brain*, BLOOMBERG NEWS, Aug. 18, 2011. These computer chips are "inspired by the human brain" and are "programmed to recognize patterns, make predictions and learn from mistakes." *Id.* The technology has passed the conceptual stage, and IBM was recently awarded an additional $21 million in DoD funding "to bring the chips to scale for production." *Id.* A cognitive computer can "react to taste, touch, smells and sound," and the "devices reach decisions

According to public records, current neuroscientific studies include: (1) the development of new drugs that can reduce fear or inhibition, suppress memory, or keep soldiers awake and alert for days; (2) novel forms of brain scanning; (3) brain-to-computer interfaces; and (4) neuromodulation.[216] Military researchers have been working to "develop the technologies needed to measure and track a subject's cognitive state in real-time."[217] Through research in brain-to-computer interfaces, scientists aim to create a mechanism by which soldiers can communicate via thought alone.[218] These studies include systems that can relay messages, such as images and sounds, between human brains and machines, or even from human to human.[219]

The military anticipates that brain-to-computer interfaces will serve a multitude of purposes.[220] These include converting neural activity for use in technological mechanisms and treatment modalities and using neural activity to remotely control vehicles and detect danger on the battlefield.[221] Another goal is to create a means by which service members can receive commands via electrodes implanted in their brains or be wired directly into the equipment they control.[222] Harnessing neural activity through non-invasive technologies, such as "dry" EEG caps, has shown great promise.[223]

In one recent study, "a monkey in North Carolina transmitted its thoughts halfway around the world to set a Japanese robot in motion."[224] Thought-control technologies through brain-to-computer interfaces are currently undergoing human clinical trials, and humans have been able to perform tasks that include turning on a TV, opening an e-mail, and spelling out words on a computer screen.[225] Another means of communicating via thought alone is

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through integrated memory, computation and communication cores that resemble synapses, neurons and axons, respectively, in the brain's nervous system." *Id.*

[216] *See* Tennison & Moreno, *supra* note 8, at 1.

[217] MORENO, *supra* note 8, at 51 (quoting Dylan D. Schmorrow & Amy A. Kruse, *DARPA's Augmented Cognition Program—Tomorrow's Human Computer Interaction from Vision to Reality: Building Cognitively Aware Computational Systems*, IEEE SEVENTH CONFERENCE ON HUMAN FACTORS AND POWER PLANTS, Sept. 2002, at 7-1).

[218] *See* Hoag, *supra* note 8, at 796. The development of brain-to-computer interfaces dates back to the 1960s, when researchers placed electrodes into the brains of monkeys in an attempt to record neural activity. *See id.*; *see also* Rachel Ehrenberg, *For Coffee Break, Woman Guides Robotic Arm with Her Thoughts*, SCI. NEWS, June 16, 2012, at 6 (outlining history of thought-control devices).

[219] *See* Hoag, *supra* note 8, at 796–97.

[220] *See* Tennison & Moreno, *supra* note 8, at 1.

[221] *See id.*

[222] *See* Hoag, *supra* note 8, at 796.

[223] Tennison & Moreno, *supra* note 8, at 1.

[224] Susan Gaidos, *Mind-Controlled: Linking Brain and Computer May Soon Lead to Practical Prosthetics for Daily Life*, SCI. NEWS, July 2, 2011, at 26 (highlighting civilian uses of brain-to-computer interfaces).

[225] *See id.* at 26–27.

through a "thought helmet." DARPA is funding research that aims to develop a helmet that will use sensors to read the brain waves of soldiers, translate the brain waves into audible radio messages, and transmit the messages to others.[226]

A primary area of research is on increasing alertness, and DARPA is spending no less than $100 million to counteract sleep deprivation.[227] Through implanted electrodes, the military is researching whether neurostimulation can improve impaired cognitive performance and reduce the effects of sleep deprivation on soldiers.[228] According to DARPA, "[e]liminating the need for sleep while maintaining the high level of both cognitive and physical performance of the individual will create a fundamental change in warfighting and force employment."[229]

This research dovetails with two other DARPA endeavors: the "Continuous Assisted Performance" program and the "Applications of Biology to Defense Applications" program.[230] The former is "investigating ways to prevent fatigue and enable soldiers to stay awake, alert, and effective for up to seven days straight without suffering any deleterious mental or physical effects and without using any of the current generation of stimulants."[231] The latter incorporates neuroscientific studies such as:

- Biological approaches for maintaining the warfighter's performance, capabilities[,] and medical survival in the face of harsh battlefield conditions;
- Biological approaches for minimizing the after-effects of battle injuries, including neurotrauma from penetrating and non-penetrating injuries as well as faster recuperation from battlefield injury and wounds;
- Biomolecular motors and devices;
- Micro/nano-scale technologies for non-invasive assessment of health . . . .;
- [T]echniques for . . . decoding . . . neural sign[als] in real time . . . .;
- Novel interfaces and sensor designs for interacting with the central . . . and peripheral nervous systems . . . .; and
- New approaches for understanding and predicting the behavior of individuals and groups, especially those that elucidate the neurobiological basis of behavior and decision making . . . .[232]

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226 *See* Halpern, *supra* note 215, at 35.

227 *See* MEHLMAN, *supra* note 20, at 19.

228 *See* MORENO, *supra* note 8, at 127.

229 *Id.* at 117.

230 *See id.* at 11–13. Another example is DARPA's "Preventing Sleep Deprivation" program, where the agency's goal is to prevent the "degradation of cognitive performance due to sleep deprivation." *Id.* at 117.

231 *Id.* at 11 (quoting Tony Tether, *Statement to the Subcommittee on Terrorism, Unconventional Threats and Capabilities*, Mar. 27, 2003, at 12, *available at* http://www.darpa.mil/WorkArea/DownloadAsset.aspx?id=1778).

232 *Id.* at 12–13.

Military researchers are also exploring optogenetics as a way of generating brain-based sensory feedback from soldiers.[233] Optogenetics "enables 'precise, millisecond control of specific neurons'" and may be used in connection with brain interfaces.[234] For example, portable technologies like near infrared spectroscopy could detect deficiencies in a soldier's neurological processes and transmit this information into a device that utilizes "in-helmet or in-vehicle transcranial magnetic stimulation (TMS) to suppress or enhance individual brain functions."[235] Findings suggest that TMS can be used to address soldier fatigue, enhance mood and social cognition, and improve memory and learning.[236] Along with TMS, transcranial direct current stimulation, which also is a non-invasive and DARPA-sponsored technology for neuromodulation, shows promise for enhancement of learning and memory.[237]

DARPA-sponsored research has also examined methods of gathering a soldier's neurological activity during battle in order to modify the soldier's equipment in real time.[238] For example, a "cognitive cockpit" would record "a pilot's brain activity to customize the cockpit to that individual's needs in real time, from selecting the least burdened sensory organ for communicating information to prioritizing informational needs and eliminating distractions."[239] Other research endeavors aim to create binoculars "that convert subconscious, neurological responses to danger into consciously available information."[240]

Additional neuroscience-related projects funded by DARPA include "Accelerated Learning," "Neurotechnology for Intelligence Analysts," and "Cognitive Technology Threat Warning System."[241] While the research includes "traditional psychological tactics used in earlier wars," the "'neuroweapons' have the capacity to profoundly change the way war is fought."[242] For example, the researchers are exploring psychopharmacological drugs that enhance aggressiveness in soldiers, make prisoners talk, and deadly

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[233] *See* Tennison & Moreno, *supra* note 8, at 2.

[234] *Id.* (quoting Mikhail A. Lebedev et al., *Future Developments in Brain-Machine Interface Research*, 66 CLINICS, supp. 1, June 2011, at 28).

[235] *Id.*

[236] *See id.* The interfaces could be linked with a wealth of online information, such as Google's book-scanning project. According to a Google engineer, the primary goal of the project "is to allow smart machines to read the books, not people." Jim Holt, *How the Computers Exploded*, N.Y. REV. BOOKS, June 7, 2012, at 34.

[237] *See* Tennison & Moreno, *supra* note 8, at 2.

[238] *See id.* at 1.

[239] *Id.*

[240] *Id.* at 1–2.

[241] *See* Laura Sanders, *Brains May Be War's Battlegrounds: Neuroscience Discoveries Could Lead to Defense Applications*, SCI. NEWS, Dec. 17, 2011, at 14.

[242] *Id.* ("The list includes a neurotoxin from a shellfish that is water soluble, can be aerosolized, and causes death within minutes; a bacterium that can induce hallucinations, itchiness and strange tastes; and an amoebic microbe that crawls up the olfactory nerve to invade the brain, where it kills brain tissue.").

toxins that shut down brain activity within minutes.[243] Researchers are also examining the development of drugs that can erase memories, which could be applied to soldiers so that they "wouldn't remember atrocities they committed" or to detainees so they "couldn't recall their own torture."[244]

Though DARPA-funded research is often cutting-edge and visionary, over 90% of its projects fail.[245] Those that succeed, however, often prove transformative for both military and civilian life.[246] The successes do carry a number of risks. For example, the President's Council on Bioethics expressed concern that use of drugs that eliminate fear or inhibition may turn soldiers into "killing machines" without trembling or remorse.[247] As the Council warned, "[s]uch biotechnical interventions might improve performance in a just cause, but only at the cost of making men no different from the weapons they employ."[248] Nevertheless, DARPA and the DoD are aggressively moving forward with the development of biomedical enhancements.[249] As one DARPA official explains, "DARPA is about trying to do those things, which are thought to be impossible, and finding ways to make them happen."[250]

While DARPA's ambitious and commendable mission often leads to combat-related innovations, the military must remain mindful of the long-term effects on service members.[251] Charles Hoge, a military physician at the Center for Psychiatry and Neuroscience at the Walter Reed Army Medical Center, has written extensively on war's impact on soldiers and veterans, particularly in the area of mental health.[252] As Hoge explains, not only are current treatment regimens inadequate, war-related PTSD often is characterized by "symptoms"

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[243] *Id.* The desire to eliminate fear in soldiers dates back at least to 1947, when a report found that only fifteen to thirty percent of soldiers actually fired their weapons in combat. *See* MORENO, *supra* note 8, at 65. This spawned countless studies in personality characteristics that would enable soldiers to function more aggressively. *See id.*

[244] Sanders, *supra* note 241, at 14; *see also* Tennison & Moreno, *supra* note 8, at 2 (noting that preliminary evidence indicates that propranolol may serve to dampen memories).

[245] *See* MORENO, *supra* note 8, at 12.

[246] *See id.*

[247] Annas & Annas, *supra* note 6, at 290.

[248] *Id.* (citing PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 199, at 154–55).

[249] *See* MORENO, *supra* note 8, at 12.

[250] *Id.*

[251] As Peter Singer explains, "[T]he Pentagon's real-world record with things like the aboveground testing of atomic bombs, Agent Orange, and Gulf War syndrome certainly doesn't inspire the greatest confidence among the first generation of soldiers involved [in human enhancement]." PETER W. SINGER, WIRED FOR WAR: THE ROBOTICS REVOLUTION AND CONFLICT IN THE 21ST CENTURY 377 (2009).

[252] *See* Hoge, *supra* note 156, at 549.

in the civilian world that are "highly adaptive in combat, fostered through rigorous training and experience."[253]

Countless books and articles have explored the role of biomedical enhancement in human society, while presidential commissions have issued reports on the ethical issues of human enhancement.[254] As one recent report argues, since physicians serve as gatekeepers for many medical products, considering the opinions of physicians is particularly informative.[255] Although only 30% of the surveyed physicians disagreed or strongly disagreed with the statement "I have no problem with medical enhancement so long as it is safe for the individual receiving it," 88.6% indicated that they would not prescribe a drug that makes soldiers more aggressive, and 71.4% indicated that they would not prescribe a drug that reduces fear in people with dangerous jobs.[256] A significant majority, 85% and 68% respectively, indicated that such medicines should be discouraged.[257]

The government must be mindful of physicians' professional judgment as it relates to use of medical products to enhance soldiers, particularly when such uses have not been approved by the FDA. For biomedical enhancements, in addition to more research on risks and benefits, there is an imminent need for "enforceable policies" that "protect individuals from coercion."[258]

III. AN EVOLVING LEGAL AND BIOETHICAL FRAMEWORK FOR MILITARY MEDICINE AND RESEARCH

Military medicine and research do not occur in a regulatory vacuum. The mustard gas, radiation, biological warfare, and psychotropic drug experiments

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[253] *See id.* According to Hoge, "[H]yperarousal; hypervigilance; and the ability to channel anger, shut down (numb) other emotions even in the face of casualties, replay or rehearse responses to dangerous scenarios, and function on limited sleep are adaptive in war." *Id.* According to one author, these factors should serve as mitigating circumstances for those who commit capital crimes. *See* Anthony E. Giardino, *Combat Veterans, Mental Health Issues, and the Death Penalty: Addressing the Impact of Post-Traumatic Stress Disorder and Traumatic Brain Injury*, 77 FORDHAM L. REV. 2955, 2995 (2009). As Giardino, an attorney and major in the U.S. Marine Corps, argues, since "military personnel have been conditioned to kill, desensitized to the act of killing, and taught to deny to themselves that they have in fact killed, combat veterans who suffer from the judgment-altering effects of PTSD and TBI are less culpable than others suffering from the same mental illness." *Id.* at 2964–65.

[254] *See* Timothy D. Hotze et al., *"Doctor, Would You Prescribe a Pill to Help Me . . . ?": A National Survey of Physicians on Using Medicine for Human Enhancement*, 11 AM. J. BIOETHICS 3, 3 (2011).

[255] *See id.* at 4.

[256] *See id.* at 6–7 tbls.2 & 3.

[257] *See id.* at tbl.3.

[258] Henry Greely et al., *Towards Responsible Use of Cognitive-Enhancing Drugs by the Healthy*, 456 NATURE 702, 704 (2008).

were each conducted under a framework for human-subjects research, albeit one that had been evolving gradually. From the eyes of the individual patient or human subject, of integral importance are the regulatory protocols governing risk-benefit disclosures and informed consent and the extent to which violations of the protocols give rise to legal remedies. At a societal level, justice requires fairness and beneficence in the selection and treatment of individuals.[259] This Part explores these concerns and focuses on legal, regulatory, and ethical doctrines that are particularly relevant to a contemporary analysis of military medicine and research.

The literature is ripe with scholarship that details regulations governing human-subjects research and the evolution of informed consent requirements in the United States.[260] While some American courts in the first half of the twentieth century recognized the importance of obtaining informed consent prior to experimental research or unapproved use of medical products,[261] physicians and researchers largely self-regulated their work pursuant to ethical canons such as the *Hippocratic Oath*.[262] At the same time, however, physicians and researchers were mindful not "to place any burdensome restrictions on research."[263] Notwithstanding the American norm of self-regulation, U.S. prosecutors involved in the Nuremberg Doctors Trial drafted "the rules" governing research on human subjects that, American prosecutors argued, "without equivocation . . . had been 'well established by custom, social usage and the ethics of medical conduct.'"[264]

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[259] *See* Charles R. McCarthy, *The Evolving Story of Justice in Federal Research Policy*, *in* BEYOND CONSENT, *supra* note 23, at 24; *see also* SHAMOO & RESNIK, *supra* note 104, at 246 ("Human experimentation raises an ethical dilemma addressed by moral philosophers since antiquity—the good of the individual versus the good of society. . . . Thus, a central ethical question in all research with human subjects is how to protect the rights and welfare of individuals without compromising the scientific validity or social value of the research.").

[260] *See generally* CARL H. COLEMAN ET AL., THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS (2005); SHAMOO & RESNIK, *supra* note 104; Efthimios Parasidis, *Compensation for Research-Related Injuries Involving Human Participants*, 2 HARV. J. MED. ETHICS 26 (2001).

[261] *See* Annas, *supra* note 98, at 22.

[262] *See* ERIN D. WILLIAMS, CONG. RESEARCH SERV., RL32909, FEDERAL PROTECTION FOR HUMAN RESEARCH SUBJECTS: AN ANALYSIS OF THE COMMON RULE AND ITS INTERACTIONS WITH FDA REGULATIONS AND THE HIPAA PRIVACY RULE, CRS-12 (2005); SHAMOO & RESNIK, *supra* note 104, at 239. As Shamoo and Resnik explain, "According to a view that has held sway among scientists, humanists, and the general public for centuries, science is objective . . . and ethics are subjective, so scientists need not deal with ethical issues and concerns when conducting research." *Id.* at 4–5.

[263] SHAMOO & RESNIK, *supra* note 104, at 239–40. Prior to World War II, "[m]ost physicians . . . did not think that informed consent was always necessary." *Id.* at 240. While the American Medical Association "considered adopting a code of ethics for research on human subjects" for decades, it did not do so until 1946. *Id.*

[264] HUMAN RADIATION EXPERIMENTS REPORT, *supra* note 2, at 76. The Nuremberg Doctors Trials were conducted by the International Military Tribunal between 1945 and

Published in 1947, the Nuremberg Code sets forth international standards for human-subjects research—standards that were not officially adopted by the United States despite its role in the prosecution of the German scientists.[265] In 1953, the U.S. military used the Nuremberg Code as a framework for internal regulations that sought to protect human subjects involved in military research.[266] At the time, however, Secretary of Defense Charles Wilson stamped the policies "TOP SECRET" and ordered that the guidelines be classified.[267] As Moreno explains, "Pentagon planners were convinced of the moral superiority of their intentions compared with those of other nations."[268] Although the regulations remained classified for over two decades, "there is little doubt commanders and investigators involved in the use of volunteers in research" were aware of informed consent protocols, since written informed consent documents were used in some studies.[269]

Once the atrocious conduct of doctors and researchers working on behalf of the U.S. government in the Tuskegee Syphilis Study became public,[270] the ensuing outrage prompted congressional investigations and enactment of federal regulations governing human-subjects research.[271] In 1981, following the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the National Commission),[272] and

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1947. *See id.* at 76–78. Following the conclusion of World War II, lawyers commissioned by the U.S. military charged twenty-three Germans (including twenty doctors) with "murders, tortures, and other atrocities committed in the name of medical science." *Id.* at 75. Army representatives during the Nuremberg trial admitted that the aforementioned ethical standards were "a matter of common practice." *Id.* at 78. In defending their actions, the Germans relied on forced sterilization and eugenics practices in the United States. *See* SHAMOO & RESNIK, *supra* note 104, at 240.

[265] *See* Annas, *supra* note 98, at 20–21. The Nuremberg Code "requires that the informed, voluntary, competent, and understanding consent of the research subject be obtained." *Id.*

[266] Earl Lane, *Ethics Code for Radiation Experiments Was a Secret*, SEATTLE TIMES, May 19, 1994, at A7.

[267] *See id.*

[268] *See* MORENO, UNDUE RISK, *supra* note 42, at 174.

[269] Lane, *supra* note 266, at A7. However, since "the ethical rules based on Nuremberg were never really embraced by the military-medical establishment, . . . the ethics policy was easily forgotten." MORENO, UNDUE RISK, *supra* note 42, at 180.

[270] *See supra* note 21.

[271] *See* WILLIAMS, *supra* note 262, at 13–14; *see generally* Brandt, *supra* note 21; Thomas & Quinn, *supra* note 21; Vicki S. Freimuth et al., *African Americans' Views on Research and the Tuskegee Syphilis Study*, 52 SOC. SCI. & MED. 797 (2001).

[272] The National Commission was charged with the mission of identifying "the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects" and developing "guidelines which should be followed to assure that such research is conducted in accordance with those principles." NAT'L COMM. FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, THE BELMONT REPORT: ETHICAL

publication of the Belmont Report,[273] the U.S. Department of Health and Human Services (HHS) set forth a uniform set of regulations governing human-subjects research that is referred to as the Common Rule.[274]

The Common Rule provides the foundational requirements for federally funded human-subjects research. These requirements include informed consent by research participants, a review of proposed research by an institutional review board (IRB), and institutional assurances of compliance with federal regulations.[275] DARPA, the DoD, the VA, and the Central Intelligence Agency (CIA) have each adopted the Common Rule, and the DoD has also promulgated a directive that provides additional protections for human-subjects research.[276]

In addition to the Common Rule, FDA regulations provide comprehensive protections for human subjects, regardless of funding source, for investigational research related to medical products.[277] In 1990, at the request of the DoD, the FDA promulgated an interim rule that allowed for a waiver of the informed consent requirements for investigational medical products if the intended use involves combat-related military exigencies. At the time, FDA guidelines permitted investigational use for treatment purposes, but only after a patient provided informed consent to the use.[278]

The new rule granted the FDA the discretion to waive the informed consent requirement if, upon application by the DoD, the FDA determined that obtaining informed consent was not feasible.[279] Prior to the new rule, "not feasible" was defined to include instances where: (1) the human subject is in a "life-threatening situation" requiring use of investigational drug;[280] (2) "[i]nformed consent cannot be obtained because of an inability either to

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PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF BIOMEDICAL AND BEHAVIORAL RESEARCH 1 (1979) [hereinafter BELMONT REPORT].

[273] The fundamental ethical principles identified by the National Commission in the Belmont Report include respect for persons, beneficence, and justice. *Id.* at 4.

[274] *See* WILLIAMS, *supra* note 262, at 13–14.

[275] *See* Common Rule, *supra* note 13, at 28,016. As the National Commission states, informed consent includes three elements: information, comprehension, and voluntariness. BELMONT REPORT, *supra* note 272, at 6.

[276] *See* DoD Directive, *supra* note 13; DARPA, *DARPA-Funded Research Involving Human Subjects and/or Animals, Guidance for Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR)*, at 3; *see also* MORENO, *supra* note 8, at 174. For DARPA-funded research, each project must be approved by the DoD and an IRB. *See DARPA-Funded Research Involving Human Subjects and/or Animals*, *supra*, at 4.

[277] *See FDA Regulations Relating to Good Clinical Practice and Clinical Trials*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/scienceresearch/specialtopics/runningclinical trials/ucm155713.htm#FDARegulations (last visited Aug. 24, 2012) (listing the area of the Code of Federal Regulations applicable to medical research).

[278] 21 C.F.R. § 312.34–312.35 (1990).

[279] 21 C.F.R. § 50.23(d)(1) (1991).

[280] *Id.* § 50.23(a)(1).

communicate" with the subject or acquire consent that is legally acceptable;[281] (3) time is insufficient "to obtain informed consent from the individual's legal representative";[282] or (4) no approved or generally recognized alternative treatment is available that is equally or more effective than the investigational drug.[283] The new rule expanded this definition to include instances where obtaining informed consent would be feasible under the old definition, but there existed an actual or threatened military combat and a desire on the part of the military to use a medical product for an unapproved use without first obtaining the informed consent of service members.[284]

Pursuant to the new authority, the FDA granted informed consent waivers for use of investigational medical products on U.S. service members.[285] Service members challenged the waivers and the constitutionality of the law, but the United States Court of Appeals for the D.C. Circuit upheld the FDA rule and the decisions to apply it.[286] The court found that although in most cases "the Constitution's due process guarantee protects an individual's liberty to decide whether or not to submit to serious medical treatment . . . administering the drugs uniformly prevents unnecessary danger to troops and medical personnel . . . [and furthers the DoD's] interest in successfully accomplishing [its] military goals."[287]

The FDA rule was subsequently revoked in 1999 when Congress, through the Defense Authorization Act, granted the President the authority to waive the informed consent requirements for reasons of national security.[288] The revocation of the rule was based in part on the FDA's negative experience with the DoD during the first Gulf War.[289] The presidential waiver remains in effect, yet the statute is silent as to the criteria that the President must apply in determining whether an informed consent waiver is appropriate.[290]

Coupled with executive authority to waive informed consent, Congress established the Emergency Use Authorization (EUA), enacted as part of the Project BioShield Act of 2004, which permits use of unapproved medical

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[281] *Id.* § 50.23(a)(2).

[282] *Id.* § 50.23(a)(3).

[283] *Id.* § 50.23(a)(4); *see also* Doe v. Sullivan, 938 F.2d 1370, 1373 n.4 (D.C. Cir. 1991).

[284] 21 C.F.R. § 50.23(d)(1) (1991).

[285] *Sullivan*, 938 F.2d at 1374.

[286] *Id.* at 1382.

[287] *Id.* at 1383.

[288] 10 U.S.C. § 1107(f) (2006); FDA Interim Final Rule, *supra* note 122, at 54,185. In addition to national security interests, the President may waive the informed consent requirements if obtaining informed consent is not feasible or contrary to the best interests of the recipient. *Id.*

[289] FDA Interim Final Rule, *supra* note 122, at 54,183; *see also supra* notes 122–29 and accompanying text.

[290] FDA Interim Final Rule, *supra* note 122, at 54,185.

products in emergency circumstances.[291] As discussed, the EUA was passed in response to an injunction that halted the DoD's anthrax vaccine program.[292] For the EUA process to begin, one of three conditions must be met: (1) the Secretary of the Department of Homeland Security determines that a domestic emergency exists, or that "a significant potential" for a domestic emergency exists, where there is a "heightened risk of attack with a specified biological, chemical, radiologic, or nuclear agent or agents;" (2) the Secretary of Defense determines that there is a similar emergency or potential emergency that threatens military forces; or (3) the Secretary of Health and Human Services determines that there is a public health emergency that affects or has the potential to affect national security and that this threat involves a specified biological, chemical, radiologic, or nuclear agent or agents.[293]

If one of the aforementioned occurs, the Secretary of Health of Human Services may issue a Declaration of Emergency.[294] Thereafter, the Commissioner of the FDA, pursuant to delegated authority from HHS and after consultation with the directors of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), is authorized to issue the EUA so long as four conditions are met: (1) the agent can cause a serious or life-threatening disease or condition; (2) on the basis of the totality of available scientific evidence, "it is reasonable to believe that the medical product may be effective in diagnosing, treating or preventing" the disease or condition; (3) the known or potential benefits outweigh the known or potential risks; and (4) no approved product is adequate or available.[295] While the EUA is available for both civilian and military use, only military populations are subject to forced use of experimental products and informed consent waivers.[296]

Importantly, only 8% of drugs that enter clinical trials earn FDA approval.[297] In other words, for approximately eleven out of twelve drugs, the FDA determines that the product is not safe or effective for the intended use. These statistics are significant when one considers the EUA process and the fact

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[291] *See* Nightingale et al., *supra* note 151, at 1046. The Project BioShield Act also allocates billions of dollars for the development of biodefense vaccines and grants vaccine manufacturers "market guarantees, tax incentives, liability protections, accelerated regulatory review, and subsidized early-stage R&D." *See* HOYT, *supra* note 155, at 151–52.

[292] *See supra* notes 145–52 and accompanying text.

[293] 21 U.S.C. § 360bbb-3(b)(1) (2006); *see also* Nightingale et al., *supra* note 151, at 1048.

[294] 21 U.S.C. § 360bbb-3(b)(1) (2006); *see also* Nightingale et al., *supra* note 151, at 1048.

[295] 21 U.S.C. §§ 360bbb-3(c)(1)–(4) (2006); *see also* Nightingale et al., *supra* note 151, at 1048. The statute requires the development of a system for collecting and analyzing safety and efficacy information, and the FDA may revoke the EUA if the criteria for the EUA are no longer satisfied. *See id.* at 1049.

[296] 21 U.S.C. §§ 360bbb-3(j)(1)–(2) (2006); *see also* Nightingale et al., *supra* note 151, at 1049.

[297] *See* Editorial, *Mechanism Matters*, 16 NATURE MED. 347, 347 (2010).

that military populations may not opt-out of investigational use. Notably, the Project BioShield Act also grants manufacturers broad immunity from liability for claims arising from the use of medical products pursuant to an EUA.[298]

Coupled with these laws, the Bioterrorism Act grants the FDA the authority to approve certain medical products without testing for effectiveness in humans.[299] This is a significant exception to the standard FDA requirement that requires human testing for safety and efficacy.[300] Under the new law, if a medical product is deemed to be important and the FDA determines that it would be unethical to conduct experiments on human subjects, the need to demonstrate efficacy in humans can be waived.[301] For products where a waiver is granted, a product can gain approval if it is found to be safe in humans and effective in two animal species.[302] Pursuant to what is often referred to as the "animal-efficacy" standard, the FDA has approved combat-related products pursuant to the new guidelines.[303]

Regardless of whether a product is approved through the standard procedures or the animal-efficacy guidelines, FDA approval does not represent a moment of clarity as to a product's risks and benefits.[304] Rather, for all FDA-approved medical products, post-market research plays an integral role in revealing an accurate risk-benefit profile for "real-world" uses.[305] Despite the essential role of post-market research in framing risk-benefit disclosures that are applicable to real-world patients, the FDA's ability to require post-market studies is limited, and gross underfunding precludes the agency from enforcing post-market requirements.[306] As a result, medical products often contain disclosures that do not accurately reflect the risks to patients.[307]

In addition to the risk-enhancing factors that result from informed consent waivers and regulatory limitations, sovereign immunity significantly heightens the safety risks to service members.[308] Studies have consistently documented

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[298] 21 U.S.C. § 360bbb-3(e)(3) (2006); *see also* Nightingale et al., *supra* note 151, at 1049.

[299] 21 U.S.C. § 356-1(a) (2006); 21 C.F.R. § 314.600 (2006).

[300] 21 U.S.C. § 355(d) (2006).

[301] *Id.* § 356-1(b).

[302] *See* MORENO, *supra* note 8, at 33.

[303] 21 C.F.R. § 314.610(a)(2) (2006).

[304] *See* Efthimios Parasidis, *Patients over Politics: Addressing Legislative Failure in the Regulation of Medical Products*, 2011 WIS. L. REV. 929, 1001.

[305] *See id.* at 947–48. "Real-world" uses refer to patients who use a medical product outside the bounds of a clinical trial. *See, e.g.*, Nancy A. Dreyer & Sarah Garner, *Registries for Robust Evidence*, 302 JAMA 790, 790 (2009).

[306] *See* Parasidis, *supra* note 304, at 948–49.

[307] *See id.* at 933. The lack of post-market research for new molecular entities (which are molecules that have not been approved by the FDA for any purpose) is particularly troubling. *See id.* at 948–49.

[308] Feres v. United States, 340 U.S. 135, 146 (1950).

the risk-enhancing aspects of preemption laws in various industries.[309] With respect to the military, in instances where a federal agency violates the law, the Supreme Court has interpreted the Federal Tort Claims Act broadly to preclude the ability of service members to raise tort claims. Under the *Feres* doctrine, the military enjoys far-reaching immunity from suits for claims that arise from, or are incident to, service in the military.[310]

The scope of preemption includes situations where the government has engaged in experimental research without providing informed consent or adequate safety disclosures.[311] Moreover, courts have extended this immunity to encompass claims by service members for alleged violations of constitutional rights, including racial discrimination and sexual harassment.[312] Taken together, service members are precluded from raising tort or constitutional claims that arise from: (1) the government's exercise of a discretionary function;[313] (2) combatant-related activities;[314] and (3) activities in a foreign country.[315] This preemption extends to third parties working on behalf of the government.[316] As such, a third party can avoid liability if the government would be immune under the terms of the statute.[317]

Sovereign immunity is particularly troubling in the case of service members because they are legally obligated to take medical products if ordered to do so for the sake of their military performance.[318] According to the Uniform Code of Military Justice, soldiers are required to accept medical interventions that make them fit for duty, regardless of whether the use is investigational or off-label.[319]

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[309] *See* Parasidis, *supra* note 304, at 990–93; Jonathan Turley, *Pax Militaris: The* Feres *Doctrine and the Retention of Sovereign Immunity in the Military System of Governance*, 71 GEO. WASH. L. REV. 1, 47 (2003).

[310] *See* Turley, *supra* note 309, at 47.

[311] United States v. Stanley, 483 U.S. 669, 684 (1987).

[312] *See, e.g.*, Chappell v. Wallace, 462 U.S. 296, 299–300 (1983); Stubbs v. United States, 744 F.2d 58, 58–59 (11th Cir. 1984); Brown v. United States, 739 F.2d 362, 369 (8th Cir. 1984).

[313] 28 U.S.C. § 2680(a) (2006).

[314] *Id.* § 2680(j).

[315] *Id.* § 2680(k).

[316] *See* Yearsley v. W.A. Ross Constr. Co., 309 U.S. 18, 19–21 (1940); *see generally* Andrew Finkelman, *Suing the Hired Guns: An Analysis of Two Federal Defenses to Tort Lawsuits Against Military Contractors*, 34 BROOK. J. INT'L L. 395 (2009) (discussing parameters of tort immunity for military contractors).

[317] *See Yearsley*, 309 U.S. at 19–21. *See generally* Finkelman, *supra* note 316.

[318] *See* Annas & Annas, *supra* note 6, at 291.

[319] *See, e.g.*, United States v. Chadwell, 36 C.M.R. 741 (1965); MORENO, *supra* note 8, at 134. Although service members do not have a right to refuse medical treatment, they may obtain permission to do so for medical or administrative reasons. *See Medical Services: Immunizations and Chemoprophylaxis*, Army Reg. 40–562, §§ 2–6 (Sept. 29, 2006) [hereinafter *Medical Services*]. Permission to refuse medical treatment must be balanced against mission requirements, and religious reasons will not automatically excuse a service member from the requirement. *Id.*; *Chadwell*, 36 C.M.R. at 748.

Refusal to do so could result in disciplinary action, which may include a court-martial and dishonorable discharge from the military.[320]

The legal and regulatory framework governing military medicine and research is buttressed by a number of international doctrines and ethical principles.[321] These include the Declaration of Helsinki, set forth by the World Medical Association in 1964, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects.[322] Taken together, the doctrines promote fundamental principles of human-subjects research that include scientific validity, social value, informed consent, respect for persons, beneficence, equitable subject selection, protection for vulnerable subjects, and independent review of research protocols.[323]

IV. SOCIO-ECONOMIC DIMENSIONS OF THE ARMED FORCES

Examining the demographics of service members informs an analysis of the socio-medical impact of military medicine and research. The need for targeted reforms becomes magnified when one considers the socio-economic dimensions of the armed forces.[324] Insofar as military actions propagate discriminatory practices that have shadowed American society since its inception, there exists an indispensible ethical obligation on the part of elected officials to mitigate discriminatory effects. I begin this Part with a review of military demographics placed in socio-economic context and then turn to a discussion of the socio-medical implications of disparities in light of legal limitations on individual freedoms.

A. *Military Demographics*

Studies have consistently found that the odds of a person entering the military are correlated with family background, race, family structure, and parental education.[325] Individuals who grow up in families with lower socioeconomic status are more likely to enlist in the military, while citizens in the top income distribution are under-represented in the armed forces.[326] Those

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[320] *See, e.g.*, United States v. Washington, 54 M.J. 936, 942 (A.F. Ct. Crim. App. 2001). Other punishments include loss of rank and loss of pay. *See* James B. Roan & Cynthia Buxton, *The American Military Justice System in the New Millenium*, 52 A.F. L. REV. 185, 193–94 (2002).

[321] *See* Annas, *supra* note 196, at 2052.

[322] *See id.* These doctrines are noteworthy because they have been relied upon by American courts. *See id.*

[323] *See* SHAMOO & RESNIK, *supra* note 104, at 251–52.

[324] Freimuth et al., *supra* note 271, at 798.

[325] *See* MacLean & Parsons, *supra* note 22, at 360.

[326] *See id.* at 349, 366; Amy Lutz, *Who Joins the Military?: A Look at Race, Class, and Immigration Status*, 36 J. POL. & MIL. SOC. 167, 184–85 (2008).

who enlist in the military are less likely to have grown up with both biological parents and are more likely to come from families where the parents had less education.[327] Service members have poorer high school grades than the general population and high school students with college ambitions are far less likely to enroll in the military.[328] Less than 5% of enlisted service members have a bachelor's degree or higher.[329] When compared to the general population, enlistees had fewer years of education and were more likely to have dropped out of high school.[330]

The racial and ethnic demographics of the military also reveal informative trends. Historically, U.S. policy dictated that military service was only for whites, though in practice African-Americans were permitted to join when the military needed additional soldiers.[331] During the Revolutionary War, George Washington initially banned black participation but later changed his mind when the British offered to free slaves who fought against the colonists.[332] Union forces during the Civil War also initially prohibited black participation in the military, but by the end of the war, over 200,000 black soldiers had fought on behalf of the Union forces.[333]

Despite the Union's victory, segregation and discrimination against African-Americans was rampant in American institutions, and the military was no exception.[334] There were few black officers, which meant that black soldiers were almost always led by white officers, "including many who discriminated against their own men."[335] This discrimination continued into and past World War II.[336] In 1948, President Harry Truman issued an Executive Order that banned racial discrimination in the military.[337] President Truman viewed segregation as a form of discrimination and considered "black civil rights as a matter of national security."[338] Notwithstanding the President's Executive

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[327] *See* MacLean & Parsons, *supra* note 22, at 360.

[328] *See id.* at 349.

[329] *See* OFFICE OF THE DEPUTY UNDER SEC'Y OF DEF., DEMOGRAPHICS 2010: PROFILE OF THE MILITARY COMMUNITY iv (2011), *available at* http://www.militaryhomefront.dod.mil/12038/Project%20Documents/MilitaryHOMEFRONT/Reports/2010_Demographics_Report.pdf [hereinafter 2010 MILITARY DEMOGRAPHICS].

[330] *See* MacLean & Parsons, *supra* note 22, at 360.

[331] *See* Lutz, *supra* note 326, at 170.

[332] *See id.*

[333] *See id.*

[334] *See id.* at 170–71. Some units were segregated by ethnicity or skin tone. *Id.* at 169–72.

[335] *Id.* at 171.

[336] *See id.* at 171–72.

[337] *See* Lutz, *supra* note 326, at 172. The Order reads: "It is hereby declared to be the policy of the President that there shall be equality of treatment and opportunity for all persons in the Armed Forces without regard to race, color, religion, or national origin." Exec. Order No. 9981, 13 Fed. Reg. 4313 (July 26, 1948).

[338] *See* Lutz, *supra* note 326, at 172.

Order, units within the military, including the Army and Marines, resisted desegregation efforts.[339]

Decades after the integration order, discrimination against African-Americans "was rampant," and the U.S. military "was marked by racial strife."[340] For example, throughout the Vietnam War, military bases in the U.S. and abroad became sites of race riots.[341] After the assassination of Martin Luther King, Jr., white soldiers burned crosses and flew Confederate flags at American bases in Vietnam.[342]

In addition to widespread discrimination within the military, the draft had a disproportionate impact along class and race lines. College students could defer service, which largely shielded the middle and upper classes. Given socio-economic demographics at the time, this exemption resulted in poor people and blacks comprising a disproportionally high percentage of service members during the Vietnam War.[343] This dynamic led commentators to observe that "blacks and the poor were serving as cannon fodder."[344]

Notwithstanding widespread discrimination in the military, with the commencement of an all-volunteer army in 1973, the proportion of African-Americans in the military grew substantially.[345] In 1970, African-Americans comprised 9.8% of the military and 11% of the general population. By 2000, African-Americans were 19.8% of the military and 13% of the population.[346] This translates to over-representation of more than 52%. After the commencement of the wars in Iraq and Afghanistan, these figures began to fall, and by 2010, African-Americans comprised 17% of the armed forces and 12.6% of the general population.[347] African-American women are enlisting in the military at a rate far higher than white or Latino women; 31% of women service members are African-American, which is double the percentage of the civilian female population that identifies as African-American.[348] By contrast, white women represent 53% of the women in the military while accounting for 78% of the female civilian population.[349]

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[339] *See id.*

[340] *See id.* at 172–73.

[341] *See id.* at 173.

[342] *See id.*

[343] *See id.* at 172.

[344] Lutz, *supra* note 326, at 172–73.

[345] *See id.* at 173.

[346] *See id.* at 177.

[347] *See* 2010 MILITARY DEMOGRAPHICS, *supra* note 329, at 20; SONYA RASTOGI ET AL., U.S. CENSUS BUREAU, THE BLACK POPULATION: 2010, tbl.1 (2011), *available at* http://www.census.gov/prod/cen2010/briefs/c2010bn-06.pdf. This equates to over-representation of approximately 35%.

[348] *See* James Dao, *Black Women Are Joining the American Military at a Disproportionate Rate*, N.Y. TIMES, Dec. 23, 2011, at A14.

[349] *See id.*

African-Americans have not been the only sub-population within the armed forces to face discrimination and unjust treatment. The same year that President Truman's Executive Order commanded "equality of treatment and opportunity for all persons in the armed forces,"[350] Congress passed the Women's Integration Act of 1948, which enabled women to join the military. Women enlistees were initially capped at 2% of all soldiers, but this restriction was lifted in 1967.[351] Female representation in the military did not begin to rise until the mid 1970s,[352] and by the early 1980s, women constituted about 10% of the armed forces.[353] Today, women comprise approximately 15% of enlistees and serve in both non-combat and combat positions.[354] Adverse reactions to experimental medical products have disproportionately affected women, particularly women of child-bearing age. For example, the anthrax vaccine has caused adverse reactions in women at a rate more than twice that of men.[355] Furthermore, AVIP was implemented despite the fact that the vaccine was not evaluated for the potential to cause fetal harm or impairment of fertility.[356]

Immigrants have also endured a difficult tenure in the U.S. military.[357] Nevertheless, dating back to the Revolutionary War, immigrants and first-generation Americans have exhibited a long history of participation in battle.[358] Irish and German immigrants fought with the colonists during the Revolutionary War and for both the Union and Confederate armies during the Civil War.[359] By the beginning of the twentieth century, immigrant patterns shifted to Southern and Eastern Europe, and this shift was reflected in enlistees during World War I and II.[360] More recently, immigrants from Asia and Latin America have served in the U.S. armed forces.[361] For example, due to increased recruitment of Latinos, their percentage of service members has tripled since 1985 and is currently about 11% of the military.[362]

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[350] Exec. Order No. 9981, 13 Fed. Reg. 4313 (July 26, 1948).

[351] *See* Martin J. Watts, *The Evolving Pattern of Occupational Segregation by Race and Gender of Enlisted Personnel in the US Armed Forces, 1984-98*, J. MIL. & STRATEGIC STUD. 50, 50 (Winter 2000–Spring 2001).

[352] *See id.*

[353] *See* MacLean & Parsons, *supra* note 22, at 368.

[354] *See id.*; Watts, *supra* note 351, at 50; Dao, *supra* note 348. Although women are less likely to serve in combat, those that do report traumatic experiences and difficulties adjusting to civilian life at rates equivalent to men. *See* Dao, *supra* note 348.

[355] ANTHRAX VACCINE CONGRESSIONAL REPORT, *supra* note 134, at 86–87.

[356] *Id.* at 88.

[357] *See* Lutz, *supra* note 326, at 168.

[358] *See id.*

[359] *See id.*

[360] *See id.* at 168–69.

[361] *See id.* at 169.

[362] *See* Jennifer Hickes Lundquist, *Ethnic and Gender Satisfaction in the Military: The Effect of a Meritocratic Institution*, 73 AM. SOC. REV. 477, 480 (2008).

The government has frequently incentivized immigrant non-citizens to fight on behalf of the United States by promising citizenship or preferential treatment in citizenship application.[363] Most recently, the Immigration and Nationality Act of 2002 expedites citizenship of non-citizens who have served honorably since 9/11, while the National Defense Authorization Act of 2003 permits naturalizations to take place outside of the United States.[364] In the past decade, over 37,000 immigrants have gained American citizenship pursuant to these laws.[365]

B. *Socio-Medical Implications of Military Demographics*

The demographics of the U.S. military largely reflect and reinforce well-documented societal disparities. To the extent that the armed forces are comprised of vulnerable populations, there is an even greater need to ensure that regulations governing military medical practice and research afford adequate safeguards to all service members. The harms that may result from exploitation of a paternalistic relationship (between supervisor and subordinate) are enhanced when coupled with a second paternalistic relationship (between military physician and service member) and particularly for those populations where the military may serve as the only feasible career option or means by which entry into the United States is possible.

Historically, wartime has been a time of "altered governance . . . a time where presidential power expands, when individual rights are compromised."[366] Today, however, war is a persistent aspect of American foreign policy. Insofar as wartime is the norm, rather than the exception, legal compromises enacted to further wartime policies "can be seen as the form of law we in fact practice, rather than a suspension of an idealized understanding of law."[367]

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[363] *Id.*

[364] Lutz, *supra* note 326, at 174.

[365] *Id.*

[366] Mary L. Dudziak, *Law, War, and the History of Time*, 98 CALIF. L. REV. 1669, 1669 (2010) ("An altered rule of law in wartime is thought to be tolerable because wartimes come to an end, and with them a government's emergency powers."). This framework reflects the ancient maxim *inter arma silent leges*, which may be translated as "in time of war, law is silent." *Id.* at 1679. As Dudziak explains, however, it is more accurate to say that:

> [L]aw is, in fact, not *silent* during wartime, but it is generally assumed that law is *different* during wartime. The arguments tend to be over whether the balance between rights and security in a particular war context is the right one, and whether departures from peacetime rules are useful or regrettable.

Id.

[367] *Id.* at 1670; *see also id.* at 1672 (noting that "[i]solation from war in the late twentieth century, through the use of limited war and advanced technology, enabled the nation to participate in war without most citizens perceiving themselves to be in a wartime").

This legal shift directly affects the regulatory framework governing military medicine and research. For example, in defending its position to prohibit service members from opting-out of investigational use of medical products, the military claims that national security interests outweigh an individual soldier's "personal preference."[368] This rationale also underlies the Supreme Court's extension of *Feres* immunity to encompass claims based on the military's secret psychotropic drug experiments. The Supreme Court "has a long history of deferring to military judgment . . . [and] the Justices invariably accept arguments put forth by the military without subjecting them to constitutional scrutiny."[369] Indeed, the historical basis of sovereign immunity stems from the English common law notion that "the king could do no wrong."[370]

In many respects, the rationale behind these contentions reflects what Jill Elaine Hasday calls "mutual benefits" arguments.[371] As Hasday explains, in instances where parties share aligned interests, the law opts not to decide between conflicting demands but rather aims to promote solidarity in the face of social conflict by restricting the rights of certain individuals.[372] Hasday explores the arguments proffered by defenders of sex and race inequality, who claim that women and people of color would be better off with fewer rights and opportunities, to demonstrate why mutual benefits arguments are unconvincing.[373]

For example, proponents of chattel slavery in the United States asserted that bondage furthered the mutual interests of slaves and their white masters.[374] Members of Congress proclaimed that slavery "has been a great blessing to both of the races–the European and African"[375] and that slavery represented a "mild and beneficent guardianship."[376] American judges supported these positions,

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[368] Doe v. Sullivan, 938 F.2d 1370, 1373 (D.C. Cir. 1991).

[369] Steven B. Lichtman, *The Justices and the Generals: A Critical Examination of the U.S. Supreme Court's Tradition of Deference to the Military, 1918-2004*, 65 MD. L. REV. 907, 910 (2006).

[370] Feres v. United States, 340 U.S. 135, 139 (1950).

[371] Jill Elaine Hasday, *Protecting Them from Themselves: The Persistence of Mutual Benefits Arguments for Sex and Race Inequality*, 84 N.Y.U. L. REV. 1464, 1465 (2009).

[372] *Id.*

[373] *See id.* at 1464.

[374] *See id.* at 1508–09.

[375] *Id.* at 1508.

[376] *Id.* at 1511. While abolitionists condemned slavery as an "abyss of misery," slavery defenders insisted that slaves were living in "Eden" and that slaves in the United States were "the happiest portion of our society" and "the happiest, and, in some sense, the freest people in the world." *Id.* at 1509. Pro-slavery defenders argued that, in practice, the "free laborer" was "more of a slave than the negro, because he works longer and harder for less allowance than the slave." *Id.* at 1511. Others proclaimed that, in Great Britain, the poor and laboring classes were "more miserable and degraded, morally and physically, than [American] slaves; to be elevated to the actual condition of whom, would be . . . a most glorious act of emancipation." *Id.*

arguing that slavery promotes "the best interests of both races."[377] The Georgia Supreme Court went so far as to state that "the relation of master and slave in Georgia" is "an institution subject to the law of kindness to as great as any institution springing out of the relation of employer and employed, any where existing amongst men."[378]

Following emancipation, American scientists argued that blacks were "primitive peoples" who "could not be assimilated into a complex, white civilization."[379] African-Americans, it was argued, were "[p]articularly prone to disease, vice, and crime . . . [and] could not be helped by education or philanthropy."[380] These sentiments were shared by many in the medical profession, as well as by anthropologists, ethnologists, and biologists.[381] In particular, physicians almost universally concluded that emancipation "caused the mental, moral, and physical deterioration of the black population," a position that they ostensibly substantiated through comparative anatomy.[382]

Nearly five decades after emancipation, doctors "generally discounted socio-economic explanations of the state of black health, arguing that better medical care could not alter the evolutionary scheme."[383] During the Tuskegee experiments that continued into the 1970s, doctors, researchers, and government officials justified the egregious research protocols by stating that, in any event, blacks would not seek out or continue therapy for syphilis.[384] Of course, this position was directly contradicted by the "readiness of the test subjects to participate" in what was described to them as free health care.[385]

While the relationship between service member and the military does not rise to that between slave and slave-owner, the theoretical basis for restricting the legal rights of each is strikingly similar. For example, just as white masters argued that slaves "were inherently unable to manage their own lives,"[386] the

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[377] Hasday, *supra* note 371, at 1508–09.

[378] *Id.* at 1511.

[379] Brandt, *supra* note 21, at 21.

[380] *Id.*

[381] *See id.*

[382] *Id.* As one contemporary doctor wrote: "A careful inspection reveals the body of the negro a mass of minor defects and imperfections from the crown of the head to the soles of the feet." *Id.*

[383] *Id.* at 22. As Brandt explains, "[t]hese assumptions provide the backdrop" for the Tuskegee experiments. *Id.*

[384] *See id.* at 23.

[385] Brandt, *supra* note 21, at 24.

[386] Hasday, *supra* note 371, at 1510. As proponents of slavery claimed:

> A negro . . . [does] not generally have judgment to direct him in what is proper for him. . . . [and is] dependent upon the white race . . . for guidance and direction even to the procurement of his most indispensable necessaries. Apart from this protection he has the helplessness of a child[]—without foresight, without faculty of contrivance, without thrift of any kind.

DoD claims that soldiers cannot be trusted to make medical decisions that are in the best interest of themselves and their comrades, asserting that autonomy in determining one's exposure to investigational medical products would be detrimental to military discipline and structure. Moreover, just as legal immunities precluded slaves from suing their owners, the law broadly preempts claims by service members, even in instances where military officials have intentionally violated legal doctrines and protocols governing human-subjects research.[387]

The architects behind the regime that jeopardizes the health and well-being of service members are Congress and the Supreme Court. Congress established the Federal Tort Claims Act to limit the reach of sovereign immunity yet has failed to act in the face of the Court's specious interpretation of the statute.[388] Subsequent legislation has allowed for the elimination of informed consent requirements, which has resulted in forced "treatment" with investigational medical products. And, through the informed consent waiver, the Executive branch has joined Congress and the Judiciary in supporting coerced experimental research on service members. In sum, each branch of the government has acquiesced to the DoD's position that, left to their own devices, soldiers would not be able to make intelligent decisions related to their obligation to further national security interests.

Fresh thinking on regulations governing military medicine and research can help alleviate the concerns raised by mutual benefits arguments. As Hasday argues,

> [We] can use the reasons why historical versions of mutual benefits discourse are unconvincing to assess modern claims that all parties are better off when the law limits the rights and opportunities available to [subpopulations]. Judges, legislators, and commentators need to evaluate contemporary mutual benefits arguments carefully or they will risk reinforcing some of America's oldest and most persistent status inequalities.[389]

Insofar as the DoD's protocols for military medicine and research are paradigmatic of Hasday's concerns, amending existing laws and regulations is of paramount importance.

V. HARMONIZING NATIONAL SECURITY WITH PATIENT AUTONOMY AND HUMAN DIGNITY

As with civilian medical practice and public health research, military medicine and research "operate in an environment influenced by societal values

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Id. (footnote omitted) (internal quotation marks omitted).

[387] *See supra* notes 311–23 and accompanying text.

[388] *See infra* notes 486–521 and accompanying text.

[389] Hasday, *supra* note 371, at 1538–39.

and political ideology."[390] The government has long leveraged the concept of national security to justify a wide range of practices that not only include covert human experimentation and investigational use of medical products but also prolong detention, interrogation, and torture.[391] In his 1961 farewell address, President Dwight D. Eisenhower warned that the nature of war threatened the future of American democracy and that the nation must be mindful to not permit war and global threats to "endanger our liberties or democratic processes."[392] As Moreno highlights, however, "[t]he difficulty, of course, is that the need for the sovereign state to defend itself can easily be used as a trump card by legitimate political authorities."[393]

Since national security is a powerful, and potentially limitless, tool, "we have to rely upon some legal process to constrain state power . . . [whereby] the maximum possible transparency and accountability will have to apply."[394] The proposed reforms aim to provide a legal framework for achieving transparency and accountability and for harmonizing national security interests with fundamental notions of patient autonomy and human dignity. The proposals include: (1) amendments to legal and regulatory framework governing military medicine and research; (2) comprehensive medical monitoring and post-treatment medical care in instances of experimental use; and (3) statutory exemptions to sovereign immunity.

A. *Amendments to the Legal and Regulatory Framework Governing Military Medicine and Research*

Ensuring justice and beneficence in military medicine and research requires steadfast adherence to core concepts that include protecting patient autonomy, promoting accurate risk-benefit disclosures, ensuring that informed consent is appropriately obtained, eliminating undue influence and coercion, and accounting for socio-economic inequalities. The proposed reforms aim to harmonize these goals through amendments to the legal and regulatory

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[390] Thomas & Quinn, *supra* note 21, at 1504; *see also* SHAMOO & RESNIK, *supra* note 104, at 6 (arguing that "research always takes place within a social context" and that "[e]conomic and political interests . . . influence scientific goals, resources, and practices").

[391] *See, e.g.*, MARY L. DUDZIAK, WAR TIME: AN IDEA, ITS HISTORY, ITS CONSEQUENCES 104–07 (2012).

[392] President Dwight D. Eisenhower, *Farewell Radio and Television Address to the American People*, THE AMERICAN PRESIDENCY PROJECT, http://www.presidency.ucsb.edu/ws/index.php?pid=12086 (last visited April 26, 2012). Likely to be very much aware of the military's research programs, Eisenhower further warned that "in holding scientific research and discovery in respect, as we should, we must also be alert to the equal and opposite danger that public policy could itself become the captive of a scientific-technological elite." *Id.*

[393] MORENO, *supra* note 8, at 176.

[394] *Id.*

framework. I focus on three areas: (1) amending federal guidelines to explicitly identify service members as a vulnerable population; (2) establishing appropriate informed consent protocols and eliminating informed consent waivers; and (3) amending the EUA process for military personnel.

1. *Amending Federal Guidelines to Explicitly Identify Service Members as a Vulnerable Population*

HHS's recent advance notice for proposed rulemaking reveals that the agency believes that amendments to the Common Rule are necessary.[395] One of HHS's primary goals in revising the Common Rule is "to better protect human subjects."[396] In the advance notice, HHS highlights the need to provide protections for vulnerable populations yet does not include service members in its definition of "vulnerable."[397] This omission exacerbates well-documented inequities, and it would behoove HHS to explicitly include military personnel in its definition.

The Common Rule grants additional safeguards to populations that are "likely to be vulnerable to coercion or undue influence" so as "to protect the rights and welfare of these subjects."[398] Given the dynamics of military hierarchy, socio-economic elements, the problem of mixed agency in military medicine,[399] and the threat of severe punitive measures, there can be no question that service members are a class of individuals that is vulnerable to coercion and undue influence.[400] Military command structure, mandatory use of investigational medical products, informed consent waivers, and the threat of court-martial for non-compliance each support this characterization.[401] The fear of dishonorable discharge for refusing to ingest an investigational medical

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[395] *See* HHS Advance Notice of Proposed Rulemaking, *supra* note 27.

[396] *Id.*

[397] *See id.* at 44,517. The Common Rule identifies children, pregnant women, prisoners, and handicapped or mentally disabled individuals as vulnerable populations. 45 C.F.R. pt. 690.107(a), 690.111(7)(b) (2006).

[398] 45 C.F.R. pt. 690.111(7)(b) (2006).

[399] Mixed agency refers to circumstances where a military physician has an obligation to someone other than the patient, such as a commanding officer. *See* Sidel & Levy, *supra* note 14, at 295. Under such circumstances, an "ethical choice may be more complex and thus more difficult." *Id.*

[400] *See, e.g.*, Jonathan D. Moreno, *Convenient and Captive Populations*, *in* BEYOND CONSENT, *supra* note 23, at 111–12 (stating that military personnel are a vulnerable population in the context of experimental research).

[401] Perhaps cognizant of these concerns, a recently-issued DoD directive classifies military personnel as a vulnerable population for purposes of non-therapeutic experimental research. DoD Directive, *supra* note 13, at 2, 23. However, the directive does not encompass off-label or investigational use of medical products where the intended use is for therapeutic or prophylactic reasons. Though limited in scope, the DoD's classification is a step in the right direction.

product is paradigmatic of the concerns anticipated by regulators in including special protections for vulnerable populations.

Given the important individual and societal concerns surrounding military medicine and research, an explicit statement in the Common Rule that military personnel are a vulnerable population is preferable. Along with this classification, HHS should establish DoD-specific protocols. These could include amending military IRB protocols to require inclusion of a civilian human-subjects research expert, a retired or active duty service member with legal expertise,[402] and mandatory use of independent consent monitors.[403] In addition to guaranteeing additional safeguards for service members, amending the Common Rule will help engage a national dialogue related to justice and beneficence in military medicine and research.

2. *Informed Consent for Service Members*

Military commanders have frequently characterized experimental research as a routine part of military training.[404] This view dates back at least as far as the radiation experiments and is still offered as a reason why informed consent should not be universally required.[405] Treating service members as on-call human subjects flies in the face of medical ethics and disrupts important notions of trust and respect that underlie the special relationship between superior and subordinate. As George Annas argues, service members must be able to "trust military physicians to follow medical ethics without exception."[406]

As explained in the DoD's influential treatise, *Military Medical Ethics*,[407] a "person or soldier cannot truly be regarded as a voluntary participant in research

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[402] The initial IRB review for use of the BT vaccine during the Gulf War recommended that the military obtain informed consent prior to use. FDA Interim Final Rule, *supra* note 122, at 54,185. The military then requested review by a second IRB, which recommended use without informed consent. *Id.* It is not clear whether the first recommendation was shared with the second IRB. *Id.* This suggests that revisiting military IRB protocols may be worthwhile as one contemplates legal and regulatory reforms for military medicine and research.

[403] While current guidelines recommend use of consent monitors and an ombudsman, neither is required. DoD Directive, *supra* note 13, at 23–24.

[404] *See* Amoroso & Wenger, *supra* note 4, at 569.

[405] *See id.*

[406] George J. Annas, *American Vertigo: "Dual Use," Prison Physicians, Research, and Guantanamo*, 43 CASE W. RES. J. INT'L L. 631, 632 (2011).

[407] The U.S. Army Medical Department, through the Borden Institute, publishes comprehensive treatises "on the art and science of military medicine." U.S. ARMY MEDICAL DEPARTMENT, BORDEN INSTITUTE, THE TEXTBOOKS OF MILITARY MEDICINE, http://www.bordeninstitute.army.mil/index.html (last visited Aug. 20, 2012). Of the twenty published treatises, one is a two-volume set titled *Military Medical Ethics*. *Id.* Last updated in 2003, the volumes explore "the ongoing tension between the medical profession and the profession of arms." U.S. ARMY MEDICAL DEPARTMENT, BORDEN INSTITUTE, PUBLISHED

unless he or she is fully informed that he or she is participating in research activities, and made aware of the risks and benefits this research may entail."[408] This notion mirrors the perspective of the National Commission, which argues that "informed consent requires conditions free of coercion and undue influence" and that "[u]njustifiable pressures usually occur when persons in positions of authority or commanding influence—especially where possible sanctions are involved—urge a course of action for a subject."[409] Indeed, as the Supreme Court has indicated, the right to refuse medical treatment is integral to the doctrine of informed consent.[410]

Each service member should be afforded an opportunity to determine if they wish to participate in experimental research or be administered a medical product that has not earned FDA approval for the intended use.[411] The decision-making process should consist of a confidential discussion between a service member and a military physician, during which the service member should be provided with information related to all known or expected risks, any anticipated therapeutic benefits, treatment options in the event of an adverse event, and the ability to opt-out of the use at any time. Use of independent monitors of consent is also worth exploring.[412] Maintaining the confidentiality of the process and the soldier's decision is integral to ensuring that the potential for retaliation for non-participation is minimized.[413] Stiff penalties for retaliatory actions would further serve to incentivize superior officers against punishing service members who elect not to participate in experimental studies or ingest medical products for investigational or off-label purposes.

As a twenty-two-year veteran and officer in the U.S. Army Medical Material Development Activity explains, individual consultation with service members would not impose an undue burden on the military: "As the largest training organization in the United States, perhaps in the world, DoD clearly has the capacity and resources to provide adequate information to each service

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VOLUMES OF THE TEXTBOOKS OF MILITARY MEDICINE, http://www.borden institute.army.mil/published.html (last visited Aug. 20, 2012).

[408] Amoroso & Wenger, *supra* note 4, at 570.

[409] BELMONT REPORT, *supra* note 272, at 8.

[410] Cruzan v. Director, Mo. Dep't of Health, 497 U.S. 261, 270 (1990).

[411] *See, e.g.*, ANTHRAX VACCINE CONGRESSIONAL REPORT, *supra* note 134, at 58 (concluding that, for AVIP, service members should be provided all existing evidence and the opportunity to decide for themselves if they wish to be exposed to the vaccine—"[l]et those who decline live with what they consider a reasonable risk."). Notably, a high dose of antibiotics given within 48 hours of exposure to anthrax can reduce the death rate of unvaccinated individuals from 99% to 80%. Katz, *supra* note 141, at 1840.

[412] The DoD currently permits research monitors in a variety of research-related settings, *see* DoD Directive, *supra* note 13, at 24–25, though it is unclear how often the monitors are actually used.

[413] Current policy permits violations of patient confidentiality "in the name of military or national security." Sidel & Levy, *supra* note 14, at 298. A commanding officer can request "all medical information relevant to military performance." *Id.*

member before he or she takes or uses an investigational product."[414] A failure to do so could prove detrimental to future military efforts.

In the military context, forced use of unapproved medical products has resulted in the loss of experienced service members.[415] A Government Accountability Office (GAO) report published in 2002 found that one in three Air National Guard and Air Force Reserve pilots who left the military or changed their status cited the AVIP program as a major contributing factor, and that two in three did not support the AVIP program.[416] Notably, these service members did not have a negative opinion of vaccines in general but rather expressed concern over the off-label use of the anthrax vaccine.[417]

Importantly, no empirical evidence supports the military's position that soldiers have made, or would make, personal medical decisions that have been, or would be, detrimental to national security interests. To the contrary, dating back to the yellow fever experiments, many service members have elected to support experimental research and medicine, often remarking that such work is central to their mission and duty to the country.[418] In this respect, an all-volunteer military has the potential to support an all-volunteer military medical and research agenda.

With respect to non-therapeutic protocols,[419] a notable example is the Medical Research Volunteer Subjects (MRVS) program, which is an all-volunteer research group stationed at Fort Detrick in Maryland.[420] Service members who participate in the MRVS program must attend research briefings

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[414] FDA Interim Final Rule, *supra* note 122, at 54,182.

[415] *See* GOVERNMENT ACCOUNTABILITY OFFICE REPORT, ANTHRAX VACCINE: GAO'S SURVEY OF GUARD AND RESERVE PILOTS AND AIRCREW 3–4, 10 (2002).

[416] *Id.* at 4.

[417] *See id.* at 17.

[418] *See supra* note 37 and accompanying text.

[419] Delineating the boundary between therapeutic and non-therapeutic interventions has generated a fair amount of controversy. *See, e.g.*, SHAMOO & RESNIK, *supra* note 104, at 250 (explaining that "[a]lthough distinctions between research and practice make sense in the abstract, they become blurry in concrete cases"). In the DoD's treatise MILITARY MEDICAL ETHICS, research is defined as "a systematic investigation designed to test hypotheses, permit conclusions, and develop or contribute to generalizable knowledge." Amoroso & Wenger, *supra* note 4, at 565 (emphasis omitted). According to the treatise, included under the umbrella of experimental research is off-label use of medical products. *Id.* This characterization is also acknowledged in DoD medical guidelines, *see Medical Services*, *supra* note 319, at 19–20, and is consistent with the National Commission's view that "the general rule is that if there is *any* element of research in an activity, that activity should undergo review for the protection of human subjects." BELMONT REPORT, *supra* note 272, at 3 (emphasis added).

[420] *See* MORENO, UNDUE RISK, *supra* note 42, at 275–77 (discussing the MRVS program). In addition, "virtual patients," which are computerized models that use medical data to mimic real people, have the potential to provide an alternative or supplement to testing on humans. *See* Shirley S. Wang, *Scientists Find Safer Ways to Test Medical Procedures*, WALL ST. J., Dec. 20, 2011, at D1.

but are not required to participate in any experimental trials.[421] When a service member elects to participate in a research protocol, the service member is free to terminate his or her participation at any time and without penalty.[422]

The MRVS model promotes military research endeavors and adheres to fundamental notions of patient autonomy and human dignity. Service members report that they are treated fairly and that they feel that their participation in the studies furthers national security interests.[423] There is nothing to suggest that the MRVS framework cannot be expanded to encompass most, if not all, experimental research in the military, and it would behoove the military to consider doing so.

As Justice Benjamin Cardozo astutely remarked in 1914, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . . ."[424] The military should not serve as an exception. The informed consent waiver should be abolished,[425] and all medical-related decisions that, in the civilian world, would require consultation with a physician and informed consent should apply to military medicine and research.

3. *Amending the EUA Process for Military Personnel*

To the extent that the EUA process is utilized, civilian protocols should govern military uses. The EUA processes for civilian and military populations are analogous in many respects. Both are bound by identical protocols in terms of initiation of the EUA, the administrative agencies responsible for providing authorization at various stages of the process, and medical monitoring once emergency use has commenced.[426] The key difference relates to the opt-out provisions. Specifically, whereas civilians may opt-out of emergency use of an investigational medical product, service members do not have this option in instances where the President has issued an informed consent waiver[427] or where other coercive forces are at play.[428]

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[421] *See* MORENO, UNDUE RISK, *supra* note 42, at 279.

[422] *See id.* at 281.

[423] *See id.* at 280–81.

[424] Schloendorf v. Soc'y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914). Decades later, this position was echoed by the National Commission: "To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment . . . ." BELMONT REPORT, *supra* note 272, at 4.

[425] The sole exception should be where, on an individual basis, circumstances are such that a soldier or their surrogate cannot provide consent to emergency treatment related to medical care for an injury. *See, e.g.*, MEHLMAN, *supra* note 20, at 243 (noting that this exception has been deemed acceptable by the FDA for non-military patients).

[426] 21 U.S.C. § 360bbb-3 (2006); *see also* Nightingale et al., *supra* note 151, at 1048–49.

[427] *See* Nightingale et al., *supra* note 151, at 1049.

[428] *See supra* notes 17–20 and accompanying text.

In the civilian context, once emergency use of an investigational product has been authorized, the provider must inform each patient: (1) that the product has been approved only for emergency use; (2) of the significant known and potential benefits and risks; (3) the extent to which risks and benefits are unknown; (4) of the availability of alternative treatments; and (5) of the risks and benefits of alternative treatments.[429] Physicians and patients rely on the sponsor and government to accurately disclose this information.[430] According to the statute, civilians must also be informed of their right to refuse use of the product and their right to refuse the product for their children or others who lack the ability to provide informed consent.[431]

For medical products administered through an EUA, informed consent protocols governing human-subjects research are not applicable.[432] Nevertheless, for civilians, "to the extent practicable given the circumstances of the emergency, prospective patients will always be informed about the opportunity to accept or refuse an EUA product . . . and be given all the information necessary to make this informed choice."[433]

Under the existing legal and regulatory regime, service members are not provided with equivalent safeguards.[434] The military exceptions to information disclosure and the elimination of the opt-out provision for military populations serve to enhance health risks to service members and contravene fundamental notions of patient autonomy and human dignity. Service members should enjoy the same level of autonomy as civilians in determining whether to be exposed to a medical product approved through an EUA.[435] And, once an EUA has been issued, the military should be obligated to provide service members with risk-benefit information as required for civilian populations.

B. *Medical Monitoring and Post-Research Medical Care*

In all instances of experimental research and investigational or off-label use of medical products, the military should provide medical monitoring and post-research medical care for all service members. As medical researchers widely recognize, utilizing health information technology to actively monitor health status provides a wealth of information and helps ensure that latent health

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[429] *See* Nightingale et al., *supra* note 151, at 1049.

[430] *See id.*

[431] *See id.*

[432] *See id.*

[433] *Id.*

[434] *See id.*

[435] As Dr. Renata Engler, Chief Immunologist at the Walter Reed Army Medical Center, argued during a DoD conference on biological warfare that was held in 1999, "Every service member deserves the same quality of care as any other patient." ANTHRAX VACCINE CONGRESSIONAL REPORT, *supra* note 134, at 40.

concerns are adequately understood.[436] Neglecting medical monitoring hinders the development of toxicology and other fields and thus stunts our understanding of adverse health effects.[437] Notwithstanding the benefits of medical monitoring, long-term health-related research of combat veterans is woefully inadequate, and the military is notorious for its failure to keep adequate medical records.[438]

During policy debates at the time of the atomic experiments, the military stated that "injuries that manifest themselves years after military service are not of particular interest from a combat-readiness viewpoint."[439] This perspective has led to record-keeping that ranges "from dismal to nonexistent."[440] As Moreno explains, the lack of long-term monitoring hinders the ability "to intervene medically as early as possible in a disease process."[441]

The mustard gas experiments provide another example. As the IOM notes, "despite knowledge available in 1933 that mustard agents . . . could produce long-term debilitating health problems[,]" the DoD did not provide any "formal long-term follow-up medical care or monitoring."[442] The IOM found the lack of medical monitoring "appalling."[443] The DoD also failed to conduct any short-term follow-up medical care for the service members who were subjects of the studies.[444] Rather, soldiers were "sworn to secrecy and simply released on leave at the conclusion of the experiments. Some of these men still had blisters or evidence of skin burns upon release but were not given any instructions about how to obtain knowledgeable medical care."[445]

More recently, reports have highlighted the DoD's failure to adequately monitor health concerns related to AVIP. Despite being required to implement medical monitoring and report vaccine-related adverse events, the DoD failed to keep adequate medical records and actively discouraged reporting of adverse events.[446] The DoD's acts and omissions resulted in "[p]reposterously low

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[436] *See* IOM REPORT, *supra* note 20, at viii. For example, analysis of electronic medical records has uncovered important information related to the risk-benefit profiles of medical products. *See* Parasidis, *supra* note 304, at 964–66.

[437] *See* IOM REPORT, *supra* note 20, at ix.

[438] *See, e.g.*, Anna M. Johnson et al., *Military Combat and the Risk of Coronary Heart Disease and Ischemic Stroke in Aging Men: The Atherosclerosis Risk in Communities (ARIC) Study*, 20 ANNALS EPIDEMIOLOGY 143, 143 (2010); MORENO, UNDUE RISK, *supra* note 42, at 270; Sidel & Levy, *supra* note 14, at 298.

[439] MORENO, UNDUE RISK, *supra* note 42, at 206.

[440] *Id.*

[441] *Id.*

[442] IOM REPORT, *supra* note 20, at vii.

[443] *See id.*

[444] *See id.*

[445] *Id.*

[446] ANTHRAX VACCINE CONGRESSIONAL REPORT, *supra* note 134, at 1, 3, 34. As a congressional investigation argued: "In a culture based on chain of command and the power to compel, attempts at persuasion and education often devolve into intimidation. Labeling

adverse report rates" and a sparse medical record from which to conduct meaningful risk-benefit evaluation.[447] Rather than using medical monitoring as a way to better understand the risk-benefit profile of the vaccine and promote the health of service members, DoD personnel viewed the reporting of adverse events as a "politically sensitive" issue and sought "to avoid it."[448]

This two-part pattern of mistreatment—problematic research protocols and the lack of appropriate medical monitoring and follow-up care—continues today. As discussed, the wars in Iraq and Afghanistan have taken a large toll on the U.S. military, with many soldiers suffering from combat-related mental health problems.[449] Although the DoD has spent approximately $3 billion to treat and study TBI and PTSD, a recent GAO report found a lack of coordination for research that examines brain injuries and a failure to comply with a legal duty to track research-related expenditures.[450]

Given the impact of TBI, PTSD, and related physical and mental disorders, military physicians are increasingly faced with complicated medical diagnoses with limited information related to health outcomes and the safety and efficacy of treatment options. While studies have found that active duty soldiers are less likely to report mental health issues for fear of negative career impact,[451] for those who do seek treatment for mental health issues, follow-up medical monitoring has been notoriously lacking.[452] Insofar as combat-related health issues such as depression, PTSD, and substance abuse have been found to last "throughout the lifetime of" affected service members, and that psychopathology "may influence suicidal behavior in combat veterans due to increased problems with families [and] difficulties at work,"[453] there is a real

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opponents as 'paranoics' and ridiculing the intelligence or courage of those with legitimate questions are not the methods of modern risk communication." *Id.* at 46 (footnotes omitted).

[447] *Id.* at 1, 3.

[448] *Id.* at 38.

[449] *See* Patricia Lester et al., *The Long War and Parental Combat Deployment: Effects on Military Children and At-Home Spouses*, 49 J. AM. ACAD. CHILD & ADOLESCENT PSYCH. 310, 310 (Apr. 2010).

[450] *See* Daniel Zwerdling, *Pentagon's Spending on Key Injuries Isn't Being Tracked Well, Auditors Say*, THE TWO WAY: NPR's NEWS BLOG (Jan. 27, 2012, 11:45 AM), http://www.npr.org/blogs/thetwo-way/2012/01/27/145983863/pentagons-spending-on-key-injuries-isnt-being-tracked-well-auditors-say. The $3 billion figure is dwarfed by an estimated $60 billion spent by the Pentagon, through 2011, to combat improvised explosive devices (IEDs), which are a primary cause of TBI and PTSD. Andrew Cockburn, *Search and Destroy: The Pentagon's Losing Battle Against IEDs*, HARPER'S MAG., Nov. 2011, at 72. In 2012, the Pentagon plans to spend an additional $10.1 billion on counter-IED initiatives. *See id.* at 77.

[451] *See* Lester et al., *supra* note 449, at 318; Scotti, *supra* note 166.

[452] *See, e.g.*, Scotti, *supra* note 166.

[453] Selby et al., *supra* note 159, at 301.

and immediate need to actively monitor the health status of service members and provide appropriate care as needed.[454]

Overmedication of wounded veterans—particularly veterans suffering from TBI—underscores the importance of using health information technology to track and treat injured service members. For example, thousands of seriously injured veterans are assigned to special units called Wounded Warrior Battalions.[455] A recent report by the Pentagon found "patterns of overmedication" and soldiers who were "addicted to pain medications" in a number of battalions.[456] Battalion staff members described the conditions as a "scary situation" for the veterans and characterized the vets as being "stoned on psychotropic drugs."[457] The Pentagon also found that overmedication could be diminished, or avoided altogether, if the battalions adopt electronic databases and alerts.[458] While the Army is working to implement such electronic monitoring, as of April 2012, the Navy has yet to approve the new program of oversight.[459]

In addition to insufficient monitoring in medical protocols, the DoD's enhancement-related monitoring is inadequate. The military's off-label use of stimulants, such as modafinil, is paradigmatic of this concern.[460] Modafinil is approved for use to treat narcolepsy and other sleep disorders.[461] Its side effects include dizziness, drowsiness, confusion, nausea, tight muscles, difficulty moving and seeing, hallucinations, depression, anxiety, abnormally excited moods, and suicidal thoughts.[462] Some studies have found that modafinil can allow individuals to stay awake for more than ninety hours, though complications have arisen as to what an individual experiences when alertness

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[454] *See* IOM REPORT ON PTSD, *supra* note 156, at 349–50. One study found that "[r]egular screening of military personnel . . . may be an important way to prevent suicide in active duty personnel." Selby et al., *supra* note 159, at 304. Many service members who committed suicide "demonstrated signs of emotional deterioration during the last days of their lives." *Id.* Active monitoring could, perhaps, identify those service members who are at high risk for suicide, thus capturing valuable days during which treatment could be provided.

[455] *See* Tom Bowman, *Wounded Warriors Face New Enemy: Overmedication*, NPR NEWS (Apr. 26, 2012), http://www.npr.org/2012/04/26/151443507/wounded-warriors-face-new-enemy-over-medication.

[456] *Id.*

[457] Bowman, *supra* note 455.

[458] *See id.*

[459] *See id.*

[460] *See* MORENO, *supra* note 8, at 115.

[461] Am. Soc'y of Health-Sys. Pharmacists, *Consumer Medication Information: Modafinil*, PUBMED HEALTH, http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000196/ (last visited Sept. 7, 2012).

[462] *Id.*

begins to fade.[463] For example, some people think they are more functional than they actually are.[464]

During the wars in Iraq and Afghanistan, the military has been dispensing modafinil, amphetamines, and other stimulants in large numbers.[465] Common side effects of amphetamines include fast heartbeat, tremors, headache, dizziness, and insomnia.[466] Dexedrine, which is an amphetamine that is officially sanctioned by the U.S. Air Force for use by pilots, contains a label warning that indicates "[a]mphetamines may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or vehicles."[467] In 2002, an American pilot who was on a ten-hour mission dropped a 500-pound laser-guided bomb that killed four Canadians and injured eight others.[468] When the pilot was questioned by the military, he claimed that the amphetamines that he was ordered to take caused him to be impatient and "he rashly decided that the target was an enemy firing position."[469]

Modafinil and other stimulants used by the military have been associated with long-term health effects that have negatively affected veterans as they return to civilian life.[470] These "go" pills often need to be counterbalanced with "no-go" pills (sedatives), which raises important questions of drug dependence and adverse health events.[471] The clinical implications are troubling. Negative health outcomes are associated with inappropriate treatment and adverse side effects from medications, utilization of unproven rehabilitation procedures, the prescribing of medications for off-label or investigational indications, and the failure to address underlying conditions such as depression, PTSD, or substance abuse.[472]

To promote positive health outcomes, medical monitoring must evolve to become a requirement of military medicine and research. The exponential growth of electronic health records and medical informatics capabilities has transformed the practice of medicine and the ability to elicit meaningful clinical

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[463] MORENO, *supra* note 8, at 116.

[464] *Id.*

[465] *See* MEHLMAN, *supra* note 20, at 21. The Air Force dispensed ten milligrams of amphetamines for every four hours of flying time for single-pilot fighter missions that were longer than eight hours, and two-pilot bomber missions that were longer than twelve hours. *See id.*

[466] Annas & Annas, *supra* note 6, at 293.

[467] *Id.*

[468] *See id.* at 294–95.

[469] *Id.*

[470] *See* MORENO, *supra* note 8, at 116; Annas & Annas, *supra* note 6, at 293. One animal study found that stimulants and amphetamines may have counter-productive effects, such as causing one to prefer easier options. *See* Laura Sanders, *Slacker Rat, Worker Rat: Caffeine and Amphetamine Turn Hardworking Rodents Lazy*, 181 SCI. NEWS, May 19, 2012, at 16.

[471] *See* MORENO, *supra* note 8, at 115; Annas & Annas, *supra* note 6, at 293.

[472] *See* Hoge, Goldberg, & Castro, *supra* note 165, at 1591.

information from health data from aggregated populations.[473] For example, the VA's VistA program has long been recognized as a transformative health information technology system, and the agency has recently proposed disclosure of medical data for purposes of monitoring and evaluating patient care.[474] The DoD also emphasizes the use of electronic medical records, while recent federal and state initiatives signal a continuing priority of harnessing electronic medical records to improve health outcomes.[475]

Incorporating medical monitoring and follow-up medical care into military medicine and research is an intelligent step towards a framework that promotes health outcomes and the ethical treatment of service members. It is also one way to rebrand the VA from what some active-duty soldiers describe as "an ineffective, uncaring institution"[476] to a premier venue for quality medical care. The DoD and the VA ought to be mindful of the fact that the *Feres* doctrine does not preempt claims by veterans that allege negligence in failing to provide appropriate "follow-up examinations, supervision, or other medical treatment" after discharge from the military.[477] And, at least one court has indicated that recovery in such circumstances is "not merely consistent with [*Feres*], but also compelled by" Supreme Court precedent.[478]

C. *Statutory Exceptions to Sovereign Immunity*

Sovereign immunity traditionally has provided the U.S. government with a comprehensive shield from litigation for claims related to harms caused by government employees acting within the scope of their employment.[479] Congress debated the sensibility of the immunity for at least two decades and ultimately took action after July 28, 1945, when an army B-25 bomber crashed into the Empire State Building, killing fourteen people and causing significant damage that went uncompensated.[480] The following year, Congress passed the Federal Tort Claims Act (FTCA), which provides a limited waiver of federal sovereign immunity.[481]

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[473] *See* Parasidis, *supra* note 304, at 964–66.

[474] *See* Notice of New System of Records "Virtual Lifetime Electronic Record" (VLER)-VA, 77 Fed. Reg. 27,859 (May 11, 2012); Parasidis, *supra* note 304, at 966 n.221.

[475] *See* Medical Services, *supra* note 319, at 5–7; Parasidis, *supra* note 304, at 962–70.

[476] Scotti, *supra* note 166, at A17. As one veteran remarks, "I have close friends who . . . had gone to the V.A. because they had suicidal thoughts, only to receive a preliminary screening, a pat on the back, a prescription for antidepressants—and a follow-up appointment for several months later." *Id.*

[477] Thornwell v. United States, 471 F. Supp. 344, 349 (D.D.C. 1979).

[478] *Id.* (citing, *e.g.*, United States v. Brown, 348 U.S. 110, 113 (1954)).

[479] *See* Mark C. Niles, *"Nothing but Mischief": The Federal Tort Claims Act and the Scope of Discretionary Immunity*, 54 ADMIN. L. REV. 1275, 1282 (2002).

[480] *Id.* at 1276–79.

[481] *Id.* at 1279.

The FTCA explicitly precludes combat-related injuries from suit.[482] The Supreme Court has interpreted "combat-related" broadly, such that the reach of immunity arguably encompasses far more than what one would ordinarily consider an injury related to combat. The genesis of this expansive definition may be traced to a trilogy of cases that led to the *Feres* decision.

By the time *Feres* reached the Supreme Court, it consisted of three consolidated cases against the U.S. government. The *Feres* component involved a wrongful death suit brought by survivors of a soldier who died after an army barracks in Pine Camp, New York caught fire.[483] The plaintiffs alleged that the fire was caused by a defective heating plant and the failure to maintain adequate fire watch at the barracks.[484] The two remaining cases—*Jefferson* and *Griggs*—were medical malpractice cases. In *Jefferson*, an army doctor left a towel, measuring thirty inches long and eighteen inches wide, in the stomach of a soldier during abdominal surgery.[485] The towel was discovered eight months later, when Jefferson underwent another surgery.[486]

In *Feres*, the Court acknowledges that the FTCA does not provide guidance as to the scope of combat-related activities that are exempt from the waiver of immunity.[487] The Court also notes that, while there are no committee reports or floor debates that outline the purpose of the statute, the FTCA is the "culmination of a long effort to mitigate unjust consequences of sovereign immunity from suit."[488] As the Court concedes, as the federal government "expanded its activities, its agents caused a multiplying number of remediless wrongs—wrongs which would have been actionable if inflicted by an individual or corporation but remediless solely because their perpetrator was an officer or employee of the Government."[489]

Despite the factors that motivated passage of the FTCA, the Court elected to grant the military broad immunity from suit. Notably, *Feres* was decided in the midst of the most egregious research ever committed by the U.S. military.[490] At the time of the decision, in 1950, the military was actively engaged in the mustard gas, radiation, biological warfare, and psychotropic drug experiments.

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[482] *See* Turley, *supra* note 309, at 4.

[483] Feres v. United States, 340 U.S. 135, 137 (1950).

[484] *Id.*

[485] *Id.*

[486] *Id.*

[487] *Id.* at 138.

[488] *Id.* at 139.

[489] *Feres*, 340 U.S. at 139–40.

[490] Contemporaneous with the *Feres* decision, the Court held that membership in the Communist Party constitutes espionage under the Smith Act. Dennis v. United States, 341 U.S. 494, 516–17 (1951). As Mary Dudziak explains, "Many view the era of the Smith Act prosecutions as an example of the way law failed during the Cold War era." DUDZIAK, *supra* note 391, at 79. The Court's decisions in *Feres* and its progeny arguably serve as another example. While the Court began to scale back the reach of its decision in *Dennis*, *see id.* at 79–80, the opposite holds true for *Feres*.

The Court's decision was in line with "a long history of deferring to military judgment,"[491] and the practical impact of *Feres* was to exacerbate discriminatory practices and societal inequalities. For example, *Feres* has been used to bar claims by an African-American service member who alleged racially discriminatory punishments and assignments[492] and claims by a service member who alleged failure to prevent or address racial discrimination.[493] The *Feres* doctrine has also been invoked to bar claims by a service woman who alleged she was sexually assaulted by a superior officer[494] as well as claims raised on behalf of a deceased CIA agent who was allegedly tortured by agency personnel.[495] In each case, since the alleged conduct occurred while the

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[491] Lichtman, *supra* note 369, at 910. Dudziak provides an informative overview of the Justices' personal views on the impact of war in judicial decision making. *See* DUDZIAK, *supra* note 391, at 52–53. Dudziak also places the Court's decisions in historical context:

> Throughout the 1930s, 1940s, and 1950s, judges, legislators, litigants, and others often conceptualized rights in terms of national security. Rights could expand or contract in ways that aided war-related governance or enhanced national security. . . . When we assume that security is at issue only in temporally confined wartimes, we miss the more pervasive influence of military conflict on American law.

Id. at 60–61 (footnote omitted).

[492] Chappell v. Wallace, 462 U.S. 296, 296 (1983).

[493] Brown v. United States, 739 F.2d 362, 369 (8th Cir. 1984). Officer Dan Briscoe was repeatedly harassed by his colleagues, and on one occasion, a noose with "KKK" inscribed on it was placed on his bunk. *Id.* at 364. On another occasion, during an off-base event, colleagues placed a noose around Briscoe's neck and raised him off the ground, at which point he thought he was being attacked by a lynch mob. *Id.* Following these attacks, Briscoe "entered into a deep mental depression" and attempted suicide by shooting himself in the head. *Id.* at 363. He survived but "was severely and permanently injured." *Id.* An appellate court found that *Feres* preempts the claims against military officials under the theory that a "claim that various officers failed to perform a proper investigation strikes directly at military decisionmaking" and would undermine "the heart of the military disciplinary structure." *Id.* at 369. The court also held that the claims against service members who engaged in the off-base attack could proceed. *Id.*

[494] Stubbs v. United States, 744 F.2d 58 (8th Cir. 1984). According to the soldier, her superior ordered her to the latrine and then accosted her, touching her breasts and genital area and telling her that if she refused to have sex with him her military duty would be "rougher." *Id.* at 59. The following morning the soldier left the base on holiday. *Id.* For days, she talked repeatedly about the attack and expressed that she felt trapped because of her refusal to have sex with her superior officer. *Id.* On the day she was scheduled to return to the base, she killed herself with a shotgun blast to the head. *Id.* The court held that the attack was "incident to service" because "a relevant relationship between . . . [the] activity at the time of the incident and her military service has been shown," and that "military discipline would be impaired if [she] were allowed to maintain the suit" since it "would undoubtedly question the interaction between an officer and his subordinate." *Id.* at 60.

[495] Sigler v. LeVan, 485 F. Supp. 185, 188–89 (D. Md. 1980). Ralph Sigler, an Army counterintelligence agent with thirty years of active duty with the Army, was contemplating retirement and allegedly was assembling papers and memorabilia to write a book about his career. *Id.* Prior to his retirement, the Army ordered Sigler to Fort Meade, Maryland, the

individuals were subject to military discipline, the *Feres* doctrine served to preempt the claims.

Jonathan Turley provides a succinct summary of jurisprudence related to the *Feres* doctrine:

> Despite language in the Federal Tort Claims Act that only exempts combat-related injuries from liability, the Supreme Court engaged in what can be viewed as a quintessential exercise of judicial activism—crafting an immunity system to achieve values and objectives of its own design. In addition to the obvious harm caused to thousands of service members, this doctrine has played a significant role in maintaining a separate military society . . . despite the Framers' opposition to such a development.[496]

According to Turley, the broad shield of immunity that the Court has crafted through *Feres* and its progeny has resulted in a "level of malpractice and negligence in the military" that is much higher than that in the private sector.[497] Immunity has also encouraged the expansion of the military into collateral areas of governance.[498] While commentators and lower courts have condemned *Feres* immunity and have gone as far as to characterize it as "un-American," "the Court has dogmatically maintained the doctrine."[499] As Judge Guido Calabresi explains, the *Feres* doctrine can be traced to "willful and arguably misguided origins," and courts have allowed the doctrine to "quickly lurch[] toward incoherence."[500]

In 1987, the Supreme Court had a chance to limit the reach of *Feres* when it considered Sergeant Stanley's claims against the government for injuries related to his participation in the LSD experiments.[501] A divided Court found for the military and held that the DoD's actions fell within the bounds of immunity provided by the *Feres* doctrine. In a vigorous dissent, Justice Sandra Day O'Connor argued that:

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headquarters of the United States Army Intelligence, confined him to a motel room for nine days, and subjected him to "severe emotional distress by the use of extensive questioning, threats and intimidations." *Id.* Sigler was found dead in a motel room in the Fort Meade area, and the Maryland State Police concluded that he had committed suicide by electrocution. *Id.* at 189. The court held that *Feres* preempted all claims filed on behalf of Sigler. *Id.* at 198. The court also held that *Feres* does not bar claims by Sigler's widow and daughter in their individual capacity. *Id.*

[496] Turley, *supra* note 309, at 4.

[497] *Id.*

[498] *See id.*

[499] *Id.* at 2.

[500] Taber v. Maine, 67 F.3d 1029, 1039 (2d Cir. 1995).

[501] *See supra* notes 110–17 and accompanying text.

> [C]onduct of the type alleged in this case is so far beyond the bounds of human decency that as a matter of law it simply cannot be considered a part of the military mission. . . .
>
> No judicially crafted rule should insulate from liability the involuntary and unknowing human experimentation alleged to have occurred in this case.[502]

In a separate dissenting opinion, Justice William Brennan noted that at least 1,000 soldiers were covertly administered LSD between 1955 and 1958, and that at least one person committed suicide after being administered LSD without his knowledge.[503] As Justice Brennan remarks,

> Having invoked national security to conceal its actions, the Government now argues that the preservation of military discipline requires that Government officials remain free to violate the constitutional rights of soldiers without fear of money damages. What this case and others like it demonstrate, however, is that Government officials (military or civilian) must not be left with such freedom.[504]

Importantly, Stanley was not administered the LSD during a combat mission but rather from military researchers on a base in Maryland.[505] Along with barring claims related to the LSD experiments, the *Feres* doctrine has also been applied to preempt claims by service members injured by the radiation experiments.[506]

The Supreme Court has justified the broad reach of *Feres* by focusing on the "unique" and "peculiar" relationship between a service member and the military.[507] For example, in upholding the use of *Feres* to preempt a claim for

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[502] United States v. Stanley, 483 U.S. 669, 709–10 (1987) (O'Connor, J., concurring in part and dissenting in part).

[503] *Id.* at 688–89 (Brennan, J., concurring in part and dissenting in part).

[504] *Id.* at 689–90 (citing the mustard gas and radiation experiments as other examples).

[505] *Id.* at 671 (majority opinion).

[506] Jaffee v. United States, 663 F.2d 1226, 1228 (3d Cir. 1981).

[507] *See, e.g.*, Chappell v. Wallace, 462 U.S. 296, 299 (1983); Stencel Aero. Eng'g Corp. v. United States, 431 U.S. 666, 671 (1977); United States v. Muniz, 374 U.S. 150, 162 (1963); United States v. Brown, 348 U.S. 110, 112 (1954). Proponents of immunity also argue that service members receive compensation and have access to health care in the event of injury in the course of duty. *See* Turley, *supra* note 309, at 11–27. As the Supreme Court has noted, however, the Veterans' Benefits Act does not contain an explicit declaration that it is the exclusive remedy against the Government for a service member's injury. *Stencel Aero.*, 431 U.S. at 675 (Marshall, J., dissenting); *Brown*, 348 U.S. at 111–12; Brooks v. United States, 337 U.S. 49, 52 (1949); *see also Jaffee*, 663 F.2d at 1250 (Gibbons, J., dissenting). Furthermore, while the court has also noted the "presence of an alternative compensation system," namely, the DoD's disability pension and VA benefits, United States v. Johnson, 481 U.S. 681, 698 (1987) (Scalia, J., dissenting), reliance on this factor has not been emphasized in subsequent decisions. *Stencel Aero.*, 431 U.S. at 671–72; Brown v. United States, 739 F.2d 362, 365 (8th Cir. 1984).

racial discrimination, the Supreme Court has gone as far as to say that "no military organization can function without strict discipline and regulation that would be unacceptable in a civilian setting."[508] Other courts have argued that the *Feres* doctrine is necessary to alleviate the "fear of disrupting the military disciplinary structure."[509]

While such statements regarding military structure are arguably applicable to split-second decisions on the battlefield,[510] the intentional acts of military researchers during the radiation and psychotropic drug experiments are of a substantially different caliber such that the premise underlying *Feres* immunity is unconvincing. Rather, the egregious research methods employed by the military underscore the need for a combat/non-combat distinction for purposes of the *Feres* doctrine. The need becomes more imminent when one considers that *Feres* has been applied to bar review of alleged racial discrimination, sexual assault, and torture.[511]

The Supreme Court has sought to erase the combat/non-combat distinction by arguing that "conduct in combat inevitably reflects the training that precedes combat."[512] Yet, there is nothing in the legislative history of the FTCA that supports this reading. Moreover, had Congress intended to grant full immunity to the military, it would not have needed to qualify the exception in the FTCA as applicable to "combat-related" claims. That Congress chose to do so suggests that it intended to have claims related to non-combat military actions be actionable under the FTCA.

A significant distinction exists between training a soldier to be prepared for combat and covert experimentation with investigational drugs. One is clearly an

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[508] *Chappell*, 462 U.S. at 300. Justice Thurgood Marshall provides a compelling argument against the claim that courts are not in the position to second guess military decisionmaking. He states:

> Had the same malfunction in the pilot eject system that caused the serviceman's injuries here also caused that system to plunge into a civilian's house, the injured civilian would unquestionably have a cause of action under the Tort Claims Act against the Government. He might also sue petitioner, which might, as it has done here, cross-claim against the Government. In that hypothetical case, as well as in the case before us, there would be the same chance that the trial would "involve second-guessing military orders, and would require members of the Armed Services to testify in court as to each other's decisions and actions."

Stencel Aero., 431 U.S. at 676–77 (Marshall, J., dissenting).

[509] *Brown*, 739 F.2d at 365.

[510] *See, e.g.*, *Chappell*, 462 U.S. at 300 (highlighting the "demands of military discipline and obedience to orders" on the battlefield, noting that compliance in such circumstances does not permit "time for debate or reflection"); Roan & Buxton, *supra* note 320, at 189 (highlighting that "[m]ilitary operations *in* modern war demand split second decisions" (emphasis added)).

[511] *See supra* notes 492–500 and accompanying text.

[512] *Chappell*, 462 U.S. at 300.

anticipated component of enrollment in the military, and has risks that are apparent and understood, while the other does not. As the Supreme Court has stated, under *Feres*, an integral factual inquiry is the nature of the activity that gives rise to the claim.[513]

Through *Feres* and its progeny, the Supreme Court has extended sovereign immunity to encompass any military decision that could remotely be interpreted as affecting national security. History has demonstrated that such broad power and legal immunity encourages unnecessarily high levels of risk and that certain subpopulations are more likely than others to bear the brunt of that risk.[514]

Furthermore, it is worthwhile to reexamine the historical basis surrounding the *Feres* decision. Justice Jackson, who penned the majority opinion for the Court, had recently returned to the United States after serving as a prosecutor during the Nuremberg Trials.[515] The consolidated cases that led to *Feres* each alleged negligence, and it is highly unlikely that Jackson would have granted the military immunity had the plaintiffs alleged intentional torts related to the radiation and psychotropic drug experiments.[516] Had Jackson done so, the United States would likely have been viewed as grossly unethical and hypocritical in the eyes of the international community.[517]

Congress should revisit the purpose of the FTCA and the definition of combat-related activities and should state unequivocally that violations of human subject protections are actionable under the FTCA. For example, Congress can reaffirm that, under the FTCA only injuries sustained directly from combat actions are exempt or that immunity under the FTCA does not extend to harms resulting from intentional torts or violations of constitutional protections.[518] As Judge Gibbons of the Third Circuit has argued, "the

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[513] 348 U.S. at 113; *Brown*, 739 F.2d at 369.

[514] *See* Parasidis, *supra* note 304, at 990–93; Turley, *supra* note 309, at 47.

[515] Jaffee v. United States, 663 F.2d 1226, 1257 (3d Cir. 1981) (Gibbons, J., dissenting).

[516] *Id.* at 1259.

[517] *Id.* An internal memo, drafted by Army Colonel Art Anderson in 1990, portrays a similar concern: "A 'military' justification for involuntary receipt of investigational products because of strategic, doctrine and discipline concerns resembles all too closely the logic used by Nazi doctors to rationalize using humans in research that had predictably destructive outcomes." MORENO, UNDUE RISK, *supra* note 42, at 273.

[518] A dissenting opinion in *Jaffee*, where the Third Circuit held that *Feres* preempted claims related to the radiation experiments, supports the position that intentional torts should not be shielded by the *Feres* doctrine. *Jaffee*, 663 F.2d at 1249–50 (Gibbons, J., dissenting). As Judge Gibbons argues:

> The Twentieth Century has witnessed time and again, in this country and elsewhere, the fragility of those protections which the legal order affords against human rights violations. One of those fragile protections is the admonitory law of intentional torts, designed to require public accountability for individual conduct, official or private, going beyond the bounds of social acceptability. . . . The international consensus against involuntary human experimentation is clear. . . . That any judicial tribunal in the world, in the last fifth of this dismal century, would choose to place a

availability of a private remedy for intentional torts will encourage public accountability of the military."[519] Congress can and should act to protect American service members from the dangers of unfettered military authority,[520] and constituents should hold their elected officials accountable for doing so.[521]

VI. CONCLUSION

The military has long nurtured a culture and identity that is fundamentally distinct from civil society,[522] and the U.S. government has a history of bending

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> class of persons outside the protection against human rights violations provided by the admonitory law of intentional torts is surprising. That it should be an American court will dismay persons the world over concerned with human rights and will embarrass our Government.

Id. (citing international human rights doctrines that include the Universal Declaration of Human Rights, International Covenant on Civil and Political Rights, Geneva Convention, and Nuremberg Code).

[519] *Id.* at 1250.

[520] *See* Chappell v. Wallace, 462 U.S. 296, 301 (1983) ("It is clear that the Constitution contemplated that the Legislative Branch have plenary control over rights, duties, and responsibilities in the framework of the Military Establishment, including regulations, procedures, and remedies related to military discipline; and Congress and the courts have acted in conformity with that view."). As Moreno succinctly explains:

> Today, as in decades past, there is a basic and striking moral difference between those who willingly and knowledgeably accept the risks of potentially dangerous substances and those who are manipulated or coerced. The former are often heroes, the latter truly "human guinea pigs" undergoing undue risks. No decent society can tolerate the exploitation of its vulnerable members. When this exploitation is conducted in the name of national defense there is something rotten at the core of that society's political culture.

MORENO, UNDUE RISK, *supra* note 42, at xvi.

[521] In the absence of congressional action, courts could use the *Bivens* remedy to allow claims against military and government officials. *See* Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics, 403 U.S. 388, 396 (1971). Under *Bivens*, courts may permit actions against federal officials whose acts violate an individual's constitutional rights, even if Congress has not expressly authorized such suits. *Id.* While the Court has noted that a *Bivens* remedy will not be available when "special factors counselling hesitation" are present, *id.*, it has not categorically excluded claims against military and government officials under *Bivens*. *See, e.g.*, *Jaffee*, 663 F.2d at 1241–47 (Adams, C.J., concurring in part and dissenting in part) (arguing that a *Bivens* remedy may be appropriate in a case brought by a service member injured during the radiation experiments).

[522] *See* Turley, *supra* note 309, at 1–2 (arguing that the U.S. military maintains a "system of governance [that] constitutes a type of pocket republic . . . a largely self-contained, semi-autonomous system that governs a population larger than that of some states"); *see also* Steve Coll, *Our Secret American Security State*, N.Y. REV. BOOKS, Feb. 9, 2012, at 27, 27 (noting that the military has long "defended itself from outside investigation and oversight").

and breaking the law during times of war.[523] While the military has traditionally enjoyed great deference from civilian courts in the United States,[524] military discipline and national security interests should not grant government officials *carte blanche* to violate fundamental human rights.[525] To the contrary, Congress and the courts should work to ensure that military and intelligence agencies remain subordinate to the democratic rule of law.[526]

The motto of the American military physician is "to conserve the fighting force," yet the last decade has seen a notable shift in emphasis to enhancing the fighting force through novel applications of biomedical enhancements.[527] The nefarious conduct of military officials during the course of the mustard gas, radiation, biological warfare, and psychotropic drug experiments provides ample evidence of the "lies and half-truths" that the DoD has utilized in the name of national security.[528] Indeed, the Army Inspector General has acknowledged the "inadequacy of the Army's institutional memory" regarding experimental research.[529] When one considers socio-economic dimensions of the armed forces, this history of neglect has served to further societal inequalities.[530] As a judge on the Sixth Circuit, and former Commander in Chief

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[523] *See, e.g.*, DUDZIAK, *supra* note 391, at 136 (arguing that "[k]eeping the war powers in check requires a politics of war, and that requires a citizenry attentive to the exercise of military power"); Coll, *supra* note 522, at 27; Schuchardt, *supra* note 90, at 77.

[524] *See, e.g.*, Lichtman, *supra* note 369, at 910.

[525] As the Supreme Court has indicated:

> No man in this country is so high that he is above the law. No officer of the law may set that law at defiance with impunity. All the officers of the government, from the highest to the lowest, are creatures of the law and are bound to obey it.

United States v. Lee, 106 U.S. 196, 220 (1882).

[526] *See* Schroeter, *supra* note 69, at 153; *see also* Cassidy, *supra* note 104, at 235 (arguing that "military intervention of any type cannot be divorced from political and economic entanglements" and that "[m]ilitary action *is* political and directly affects economic affairs").

[527] *See* Annas & Annas, *supra* note 6, at 287. Just as the traditional goals of medicine have been to treat disease and alleviate suffering, the traditional goals of the military physician have been to care for physical and mental health needs of service members. *Id.*

[528] *See* IOM REPORT, *supra* note 20, at vii. The mustard gas, radiation, and psychotropic drug experiments may be properly characterized as a form of torture. *See* Smith, *supra* note 1, at 518 (citing IOM REPORT). As Beecher warned in the mid-twentieth century: "Any classification of human experimentation as 'for the good of society' is to be viewed with distaste, even alarm. Undoubtedly all sound work has this as its ultimate aim, but such high-flown expressions are not necessary and have been used within recent memory as cover for outrageous ends." Beecher, *supra* note 28, at 468.

[529] MORENO, UNDUE RISK, *supra* note 42, at 254.

[530] *See* SHAMOO & RESNIK, *supra* note 104, at 248 (indicating that scholarship has not adequately addressed the distribution of benefits and harms in human-subjects research); Freimuth et al., *supra* note 271, at 798 (discussing research that indicates race, socio-economic status, and access to health care are correlated with lack of knowledge of research protocols); Lundquist, *supra* note 362, at 478.

of the Ohio National Guard explains, "in a democracy we have far more to fear from the lack of military accountability than from the lack of military discipline or aggressiveness."[531]

Despite the Supreme Court's deference to military judgment, the Court has also indicated that service members are entitled to constitutional protections as Americans.[532] At the individual level, each service member should maintain patient autonomy and the right to refuse investigational products without fear of punitive repercussions. In the aggregate, the law should serve to instill a sense of confidence in service members that those with power will be held accountable for actions that violate individual rights. Experimentation without consent can never be justified,[533] and patient autonomy and human dignity ought not be extinguished because one elects to serve their country and defend American freedoms.

To the extent that changing levels of liability result in changing levels of accident avoidance,[534] Congress should disincentivize behavior that unnecessarily increases risks to service members by enacting legislation that limits the scope of the *Feres* doctrine. The primary purpose of military medicine must be to care for service members and veterans—to enhance each patient's expectation of recovery, reduce the severity of symptoms, and prevent long-term disability.[535]

Service members have long been "out-of-sight, out-of-mind" for both Congress and academics[536] and have endured decades of unjust treatment at the hands of the military establishment. As Justice Brennan wisely observed in *United States v. Stanley*, "[s]oldiers ought not be asked to defend a Constitution indifferent to their essential human dignity."[537] Towards this end, the proposed reforms serve to harmonize national security interests with fundamental principles of patient autonomy and human dignity. The preferred method of protecting service members and preserving military order and discipline is to religiously follow policies that promote justice and beneficence in military medicine and research.

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[531] Jaffee v. United States, 663 F.2d 1226, 1267 (3d Cir. 1981) (Gibbons, J., dissenting) (citing views of Judge Celebrezze).

[532] *See* Chappell v. Wallace, 462 U.S. 296, 304 (1983); *see also* Earl Warren, *The Bill of Rights and the Military*, 37 N.Y.U. L. REV. 181, 188 (1962) (stating that "our citizens in uniform may not be stripped of basic rights simply because they have doffed their civilian clothes").

[533] *See* Annas & Annas, *supra* note 6, at 306.

[534] *See* Turley, *supra* note 309, at 47.

[535] *See* Hoge, Goldberg, & Castro, *supra* note 165, at 1591.

[536] Turley, *supra* note 309, at 89; *see also* DUDZIAK, *supra* note 391, at 92 ("For legal scholars . . . the development of the national security state has either been largely conceded or simply ignored.").

[537] 483 U.S. 669, 708 (1987) (Brennan, J., concurring in part and dissenting in part).